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FOOD LABELING

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

Food Label Information Panel

In the FEDERAL REGISTER of March 30, 1972 (37 FR 6493), the Commissioner of Food and Drugs proposed under Title 21 a new § 1.8d, relating to establishment of a food label information panel, in conjunction with the related proposal for nutrition labeling. The Commissioner's decision with respect to nutrition labeling appears in this issue of the FEDERAL REGISTER (38 FR 2125). Because the food label information panel regulation would apply to all mandatory label requirements, in addition to nutrition labeling, it is considered separately in this final order. A total of 83 comments were received from consumers, consumer organizations, industry representatives, trade associations, and other interested persons, specifically related to the food label information panel proposal.

1. Nineteen comments questioned the legality of the proposal. Most of these stated generally that there does not seem to be any statutory authority for some of the proposed provisions in either the Federal Food, Drug, and Cosmetic Act or the Fair Packaging and Labeling Act. The comments argued that neither act gives the Food and Drug Administration the authority to require an information panel or to regulate its exact location and the size of the type to be used. It was also asserted that there is nothing in the legislative history of either act to indicate that Congress intended to delegate to the Food and Drug Administration the power to prescribe the specific location of any label declaration.

The Commissioner concludes that sections 201, 403, and 701 of the Federal Food, Drug, and Cosmetic Act contain sufficient authority for the promulgation of this regulation. Section 403(a) provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular, and section 201(n) states that the failure to include material information may be as misleading as the inclusion of false information. Section 403(f) further provides that a food shall be deemed to be misbranded if any of the information required by law to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The Commissioner has concluded that the information required to appear on the label or labeling would be misleading and lack sufficient prominence and conspicuousness to render it likely to be read and understood unless it appears in compliance with the requirements of new § 1.8d. Section 701(a) of the act provides that regulations may be issued for the efficient enforcement of the act, and accordingly this new regulation is fully authorized.

2. Three nutritionists commented in favor of a uniform location for nutrition information. The Society for Nutrition Education objected to nutrition information being restricted to either the principal display panel or the information panel, but recommended it be located in one area. The Massachusetts Consumer Council agreed with an information panel but recommended that the panel be defined in more detail concerning different package shapes and sizes. The Council on Children, Media and Merchandising objected to the defined restriction of the placement of the information panel. Forty-five members of industry and 33 trade associations, including one foreign association, also submitted comments. Some objected to the concept of an information panel as being impracticable, or recommended that the proposal concerning information panels be withdrawn. Virtually all comments from industry and trade associations objected to the requirement for placement of the information panel immediately to the right of the principal display panel as being too restrictive or as not being amenable to some products.

The Commissioner has considered all these comments. Information panels on food packages will contribute organization to labeling that will reduce confusion and promote better understanding, in the interest of consumers. In consideration of the impracticability of placing the information panel immediately to the right of the principal display panel in all cases, the revised regulation provides for variations in package shapes and sizes. If there is an impracticable panel "immediately to the right" or if the package is designed so that there is no such panel, the information panel will be permitted to appear on the next panel to the right. For example, cyclindrical containers with a principal display panel oriented along the horizontal (end-to-end) axis will be permitted to use some other part of the cylindrical surface for the required information panel rather than the container end. In cases where there are two or more alternate principal display panels, only one information panel is required, and any one of the two or more alternate principal display panels may bear the required information. Areas of space not used, e.g., between spot labels are not part of the label or information panel.

3. Several firms objected to the inclusion of certain mandatory information under § 1.8d, or objected to the requirement that this information appear either on the principal display panel or on the information panel. The Commissioner believes that this information should be easily and readily available to consumers and the requirement for placement on one of these panels is the most appropriate means of assuring this availability. Therefore, this requirement remains unchanged.

4. Concerning the minimum type size requirement of 1/16 inch there were comments that this provision is unnecessarily rigid and impractical, particularly with respect to small labels. Lesser minimum type sizes were suggested. Several comments expressed concern that certain existing labels, e.g., a milk bottle or soda pop bottle cap provide insufficient space to accommodate the information that would be required in view of the new nutrition labeling requirements under § 1.17. The Commissioner agrees that type size is only one of the elements which determines conspicuousness; however, type size is an important element that can be readily measured. Therefore, the final regulation retains a uniform type size and placement requirement, but provides that any interested person may petition the Commissioner to establish, where justified, a smaller type size or an alternative means of disseminating such information to consumers.

5. Exemptions were requested from the requirements of § 1.8d for random food packages, margarine, and salt on the basis of conflict with existing regulations. Section 1.1c (21 CFR 1.1c) exempts random food packages from certain requirements for declaration of quantity of contents. The standard of identity for margarine § 45.1 (21 CFR 45.1) requires ingredients to be stated on the principal display panel immediately preceding or following the name of the food. Section 3.87 (21 CFR 3.87) requires labels of salt and iodized salt to bear statements concerning iodide to appear on the principal display panel. The Commissioner concludes that existing regulations concerning random food packages, salt, and margarine do not conflict with the requirements of § 1.8d, and that there is no reason for exempting these products from the requirements. Those existing regulations remain effective and are not changed by § 1.8d.

6. In response to other concerns expressed in the comments, the Commissioner advises that:

(a) The term "label" is defined in section 201(k) of the Federal Food, Drug, and Cosmetic Act to mean "a display of written, printed, or graphic matter upon the immediate container of any article * * *."

(b) Information required by the regulation may be repeated in whole or in part elsewhere on the label, provided it is not misleading.

(c) Information not required to appear on the principal display panel or information panel is not subject to the type size restrictions.

The Commissioner concludes, having considered the comments received and other relevant material, that the proposed regulation with changes, should be adopted as set forth below.

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic

Act (secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055; 21 U.S.C. 321, 343, 371(a)), and under authority delegated to him (21 CFR 2.120), Part 1 is amended by adding a new § 1.8d, as follows:

§ 1.3d Food labeling; information panel.

(a) The term "information panel" as it applies to packaged food means that part of the label immediately to the right of the principal display panel as observed by an individual facing the principal display panel with the following exceptions:

(1) If the part of the label immediately to the right of the principal display panel is too small to accommodate the necessary information or is otherwise unuseable label space, e.g., folded flaps or can ends, the panel immediately to the right of this part of the label may be used.

(2) If the package has one or more alternate principal display panels, the information panel is immediately to the right of any principal display panel.

(3) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(b) All information required to appear on the label of any package of food pursuant to §§ 1.8a, 1.8c, 1.10, 1.17, 1.18, and Parts 80 and 125 of this chapter shall appear either on the principal display panel or on the information panel unless otherwise specified by regulations in this chapter.

(c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than 1/16 inch in height unless an exemption pursuant to paragraph (e) of this section is established. The requirements for conspicuousness and legibility shall include the specifications of §§ 1.8b(h) (1) and (2) and 1.9.

(d) All information appearing on the principal display panel or on the information panel pursuant to this section shall appear on the same panel unless there is insufficient space. If there is insufficient space for all of this information to appear on a single panel it may be divided between these two panels except that the information required pursuant to any given section or part shall all appear on the same panel.

(e) If the label of any package of food is too small to accommodate all of the information required by §§ 1.8a, 1.8c, 1.10, 1.17, 1.18, and Parts 80 and 125, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than 1/16 inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted to the Hearing Clerk in the form established in § 2.65 of this chapter.

Effective date. All labeling ordered after December 31, 1973, and all labeling used for products shipped in interstate commerce after December 31, 1974 shall comply with this regulation.

(Secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055; 21 U.S.C. 321, 343, 371(a))

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

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PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

Nutrition Labeling

In the FEDERAL REGISTER of March 30, 1972 (37 FR 6493), the Commissioner of Food and Drugs proposed a new section on nutrition labeling under Title 21. Individuals and organizations submitted 3,140 comments on the proposal. These included 2,863 comments from individual consumers, 71 from consumer groups and dietetic associations, 57 from professionals, 24 from representatives of governmental agencies including State and local groups, 84 from food manufacturers and distributors, and 41 from trade associations. Comments received from all of these groups and individuals strongly favored nutrition labeling, with the exception of 23 replies which contained negative views of the basic concepts of the proposal.

Mandatory nutrition labeling. Some 290 consumers and 15 consumer groups believe that nutrition labeling should be mandatory for all foods. The Commissioner has concluded that insufficient information is known about the nutrient content and variability of some foods, and that the analytical methodology and capability of some food manufacturers, processors, and distributors is inadequate to permit adoption of a requirement at this time that all foods bear nutrition labeling. Experience under this new regulation is required before expansion to all foods on a mandatory basis can be considered.

Percentage labeling. Some 17 consumer groups requested percentage labeling of at least major food ingredients, e.g., the percentage of fruit juice and fruit drinks. The Commissioner has proposed a separate regulation dealing with this subject in the FEDERAL REGISTER of June 22, 1972 (37 FR 12327), and a final order will be issued on it in the near future.

Applicability of nutrition labeling. Numerous comments requested clarification of the circumstances under which nutrition labeling will and will not be applicable, and particularly the relationship between nutrition labeling and special dietary food labeling under 21 CFR Part 125. The final regulation clarifies both of these points.

Except for some standardized foods, the decision to add a vitamin or mineral to, or make a nutritional claim for, a food is entirely voluntary. The Commissioner has therefore concluded that, where a nutrient is added to a food, e.g., the addition of vitamin C to a breakfast drink, or a claim or information with respect to nutritional properties of a food is included in labeling or advertising, e.g., the amount of vitamin C in orange juice, or the fact that orange juice is a good source of vitamin C, or a general or specific reference to the caloric or fat content of a food, or any other representation that a food is useful in the daily diet because of any of the nutrient qualities covered in this regulation, the full nutrition labeling established in this regulation must be utilized. Only by having available this full nutrition labeling for a food to which such a nutrient is added or for which such claim or information is provided can such claim or information be evaluated and understood, and the food properly used in the diet. Without full nutrition labeling such claims or information would be confusing and misleading for lack of completeness, and could deceive consumers about the true nutritional value of the food, its overall nutritional contribution to the daily diet, and its nutritional weaknesses as well as strengths. Since addition of nutrients and use of nutrition claims or information is voluntary in most cases, the application of this new regulation on nutrition labeling is also voluntary. A manufacturer who does not wish to use nutrition labeling need not add nutrients to his products or refer to their nutritional properties in labeling or advertising.

All food standards providing for addition of nutrients or labeling of nutritional qualities have been reviewed. For most food standards, the addition of nutrients is optional and nutrition labeling is therefore entirely appropriate because the manufacturer is not required to add nutrients or to label nutritional properties. For those few food standards where the addition of nutrients and/or the labeling of nutritional properties is mandatory, the Commissioner has concluded that no hardship will be imposed by the application of nutrition labeling. Accordingly, none of these standardized foods is exempted from nutrition labeling. The Commissioner will consider requests for such exemptions on an ad hoc basis, based upon a showing of undue hardship.

Several food standards for enriched foods require labeling under 21 CFR Part 125. The addition of a nutrient or the use of a nutrition claim or information has in the past uniformly required the use of labeling under 21 CFR Part 125. The Commissioner has therefore reviewed the relationship of 21 CFR Part 125 to nutrition labeling and has reconciled them in a way designed to provide the maximum useful information to consumers.

In the past, the term "special dietary food" has been defined to include any food to which a nutrient has been added or for which nutrition claims or informa-

tion have been used. This approach was adopted to assure that such foods would contain specific label information about the particular nutrient(s) involved, pursuant to regulations promulgated in 21 CFR Part 125, because until now general nutrition labeling for such foods was not considered feasible or appropriate. In fact, virtually all of the foods categorized as special dietary foods for purposes of requiring nutrient labeling have been intended for consumption by the general population and not by any particular small segment.

The development of general nutrition labeling, applicable to all foods, obviates continuation of nutrient labeling of these general purpose foods under 21 CFR Part 125, and permits replacement of this approach with broad nutrition labeling under new § 1.17 (21 CFR 1.17) as set forth below.

For some products, general nutrition labeling under § 1.17 is inappropriate and very specific special dietary food labeling under 21 CFR Part 125 is retained. These foods are exempted from § 1.17 in this final regulation. Such exempted foods include certain infant foods (for which separate labeling has been promulgated in 21 CFR 125.5); dietary supplements of vitamins and minerals (subject to a standard of identity promulgated elsewhere in this issue of the FEDERAL REGISTER as § 80.1 (21 CFR 80.1) and for which specific special dietary food labeling under 21 CFR Part 125 is appropriate); any food intended for use as the sole item of the diet (for which specific special dietary food labeling, including in some cases amino acid composition, is appropriate under 21 CFR Part 125); and foods represented for use solely under medical supervision in the dietary management of specific diseases and disorders (such as foods for the dietary management of inborn errors of metabolism, for which specific special dietary food labeling is also more appropriate under 21 CFR Part 125). In each of these instances, the broad approach adopted for nutrition labeling, which is clearly desirable for general consumer use, is inappropriate because of the need for more detailed and specific information and because the type of product involved is more readily susceptible to precise quality control of the nutrient levels.

To correct the present reference in several food standards to labeling under 21 CFR Part 125, the Commissioner is proposing elsewhere in this issue of the FEDERAL REGISTER to amend all such standards to provide that the reference be changed to new § 1.17. 21 CFR Part 125, which is the subject of a separate order published elsewhere in this issue of the FEDERAL REGISTER, also clarifies the intended application of § 1.17 by providing that the term "special dietary use" as applied to food used by man means a particular use for which an article purports or is represented to be used, including supplying a vitamin, mineral, or other dietary property for use by man to supplement his diet by increasing the total dietary intake, except for foods for which nutrition labeling is used as required pursuant to § 1.17.

The revision of 21 CFR Part 125 published elsewhere in this issue of the FEDERAL REGISTER relates only to §§ 125.1–125.3, and does not deal with § 125.6 (relating to food used in control of body weight or in dietary management with respect to disease). Although a revision of § 125.6 has been proposed and was included as part of the 1968–70 Special Dietary Food Hearings, the Commissioner has not yet acted upon this aspect of those hearings.

As already explained, any reference in labeling or advertising to protein, fat, carbohydrates, or calories will result in a requirement that the food bear full nutrition labeling pursuant to new § 1.17. Under § 125.6, which is more limited in its application than § 1.17, specific claims relating to weight control or dietary management of disease result in a requirement that the product bear a statement of the percent by weight of protein, fat, and carbohydrates, and the number of calories. In view of the wording of new § 1.17, there will be no situation in which § 125.6 will be applicable and § 1.17 will not be applicable. Moreover, § 1.17 requires that the information set out in § 125.6 be included in nutrition labeling in the format established in § 1.17. Thus, these two regulations are entirely consistent, and there is no need to amend § 125.6 to accommodate nutrition labeling at this time. The Commissioner intends to review the need for § 125.6, and to act upon the related issue of claims based upon caloric content of a food, in the context of the proposals which were the subject of the Special Dietary Food Hearings, in the near future.

Sodium declaration. Several authorities indicated the value of continuing to list sodium content of foods, without listing other nutrients, for those on a sodium-controlled diet. This need has been met by permitting the listing of sodium in milligrams per serving, without subjecting the label to the requirements of nutrition labeling. Any such label declaration must be in compliance with § 125.9. However, § 1.17 provides for the inclusion of sodium content within nutritional labeling when the manufacturer so chooses. When a sodium content declaration is included in full nutrition labeling, the sodium content declaration shall appear immediately following the statement on fat content.

Cholesterol declaration. Because of the interest of many individuals and medical authorities, the Commissioner has concluded that it is in the best interest of the consumer to permit listing of cholesterol content without subjecting the label to the requirement of full nutrition labeling. Any such label must be in compliance with § 1.18, which is published in this issue of the FEDERAL REGISTER. However, § 1.17 provides for the inclusion of cholesterol content when the manufacturer chooses. When a cholesterol declaration is included in full nutrition labeling, the declaration shall appear immediately following the fat statement.

Infant, baby, and junior food. Manufacturers of strained conventional foods for infants and children asked that they be permitted to use a standard for nutrition labeling applicable to children under 4 years of age. This has been provided for in the final order by permitting these products to utilize the recommended daily allowances for children under 4 years of age as set forth in new 21 CFR 125.1(b), which is published elsewhere in this issue of the FEDERAL REGISTER, and a corresponding average serving size.

Reference standard. The problem of selecting a proper reference standard for nutrient levels drew considerable comment. The change from use of the outdated Food and Drug Administration Minimum Daily Requirement (MDR) values to use of a standard derived from the National Academy of Sciences-National Research Council (NAS–NRC) Recommended Dietary Allowance (RDA) values was approved by all who commented. Several specialists in the area of human nutritional needs commented on the selection of the proper reference standard and its nomenclature. Most of these specialists agreed that, to be useful for labeling, the table of the NAS–NRC report "Recommended Dietary Allowances" needs simplification. Suggestions included calculating a weighted mean Recommended Dietary Allowance (RDA) value, omitting or including infants and pregnant women, and using one specific RDA group, such as the 22-to-35-year-old male or female. An NAS–NRC ad hoc Conference on Nutritional Labeling held July 24–26, 1972, in Washington, D.C., recommended use of the adult male standard, adding an allowance for vitamin D.

The need was recognized for the development of a single set of standard nutrient requirements applicable to nutritional labeling and other regulations with nutrition components. After consideration of the comments on the nutrition labeling proposal and other available information, a standard set of values, to be known as the U.S. Recommended Daily Allowances (U.S. RDA), was developed. The designation "U.S. RDA" will distinguish this set of values from any single set of NAS–NRC RDA values. These U.S. RDA values were derived from the highest value for each nutrient given in the NAS-NRC tables for males and nonpregnant, nonlactating females, 4 or more year of age, except for calcium, phosphorous, biotin, pantothenic acid, copper, and zinc.

The highest values were selected to assist all segments of the population. Further, the differences between the highest values and some specific set of values for an age or sex group or a median or mean set are generally minor. The U.S. RDA values for calcium and phosphorus (both 1 gram) are not the highest values in the above-cited NAS-NRC tables for these nutrients (both 1.4 grams), because of their physical bulk

and solubility, the wide variability in requirements depending on age (0.8 to 1.4 grams), the human requirements of approximately 1 gram generally accepted in the United States, and the lower values generally advocated by international nutrition groups, e.g., the FAO/WHO Expert Group on Calcium Requirements.

Two members of the National Advisory Food Committee to the Food and Drug Administration pointed out that the National Academy of Sciences has not tabulated RDA values for biotin, pantothenic acid, copper, and zinc, although these nutrients are now recognized as essential in human nutrition. While biotin, pantothenic acid, copper, and zinc are so widely distributed in conventional foods that it would be difficult to select a diet in which they would be deficient, they are essential nutrients and are included as optional nutrients in dietary supplements in 21 CFR 80.1. Therefore, the Commissioner has concluded that it is appropriate to include biotin, pantothenic acid, copper, and zinc, in nutrition labeling at this time. In addition, evidence of zinc deficiency in some segments of the population also supports the conclusion that zinc should be included in nutrition labeling.

It is anticipated that the U.S. RDA values will be amended periodically to concur with major changes that may be made in the National Academy of Sciences-National Research Council RDA values.

Standardized format. The Food and Drug Administration proposed a standardized format for listing seven commonly analyzed nutrients. This proposal was well received by consumers, consumer groups, and most professionals and teachers. The intense interest of consumer groups in inclusion of all seven nutrients in the standardized format has been reiterated several times. Industry, however, strongly opposed listing nutrients that were not present, emphasizing that this is a negative approach to nutrition labeling and referring to it as "negative labeling." Recognizing the validity of both views, the Commissioner has concluded that it is reasonable to require a standard seven-nutrient format unless a food contains less than 2 percent of the U.S. RDA for four or more of the seven nutrients. In the latter case, the manufacturer or distributor may list no more than three nutrients without listing the seven required by the standard format. Where the standard seven-nutrient format is not used, it is necessary to add the statement "contains less than 2 percent of the U.S. RDA of ------," listing whichever of the seven nutrients for which specific levels have not been declared.

The original proposal indicated that quantities of nutrients at levels less than 5 percent of the RDA would be considered insignificant and would have to be labeled to show consumers this fact. Suggestions were made that levels of nutrients less than the lowest increment be designated by an asterisk opposite the given nutrient or nutrients in the standard seven-nutrient format with a reference statement "less than ------ percent of the RDA." After careful consideration of these comments, the regulation has been changed to provide that nutrients present in amounts less than 2 percent of the U.S. RDA may be indicated by a zero, or by an asterisk referring to another asterisk placed at the bottom of the table and followed by the statement "contains less than 2 percent of the U.S. RDA of this (these) nutrient (nutrients)."

Labeling increments. The question of "negative labeling" is linked to the labeling increments used. Many of the objections to a standardized format disappear when the lower limit for a serving is decreased from the proposed 5 percent of the reference standard of a nutrient to 2 percent of that standard. Such small increments appear to be approaching the limits of accuracy of the analytical methods. However, practicing nutritionists pointed out that nutritionally acceptable diets could be assembled with foods that had nutrient contents that are virtually all below the proposed 5 percent cutoff value. Nutrition labeling is voluntary, and manufacturers need positive reasons for using nutrition labeling if it is to be widely accepted and of optimum value to the consumer. In recognition of these views, the regulation includes use of a standard format, but with reduction of the increments to 2 percent for levels up to and including 10 percent of the reference standard and to 5 percent for levels above 10 percent and up to and including 50 percent of the reference standard. As originally proposed, 10 percent increments of the U.S. RDA will be used for content above 50 percent.

Combination packaging. Comments were received from manufacturers asking if foods commonly combined with other ingredients could have nutrition labeling which stated nutrition information for the food plus the ingredients, e.g., a dry cake mix plus the eggs and milk required for producing a finished cake, or dry ready-to-eat breakfast cereal plus milk. Although combined values provide the consumer with a better view of the nutritional value of the food, the consumer will not realize the nutritional value of the specific product purchased if only such combined values are provided. It appears reasonable to require that the label state separately the nutrition information for the specific food product and, if the manufacturer desires, to give the nutrition information for the product plus the other ingredients in a second column of values. The manufacturer must clearly identify the other ingredients, and the quantity used as part of one serving of the final food as consumed, e.g., ½ cup of vitamin D milk, or 1 tablespoon of butter.

It was pointed out that a number of food products are comprised of two or more separately packaged ingredients enclosed in an outer container, and if nutrition information were placed on the labels of the individual packaged ingredients, the consumer would be unable to use the information at point of purchase. It is reasonable to require the manufacturer to place nutrition information on the outer container for the combination of the individual ingredients and the total product. However, when two or more food products are simply combined together in such a manner that no outer container is used, or no outer label is available, each product shall have its own nutrition information statement, e.g., two boxes taped together or two cans combined in a clear plastic overwrap.

Fortification guidelines and nutritional claims. The subject of labeling increments and "negative labeling" is inextricably involved with the problem of "nutrient races" and promiscuous fortification. Several educators and professionals cautioned that guidelines for adding nutrients were needed. Nutrition labeling is designed to provide consumers with a means for identifying the nutrition properties of a food, and is not intended to encourage or suggest that foods with apparently low nutrient content should be fortified in order to give an improved nutrition label statement. In addition to existing regulations pertaining to nutrition fortification, the Food and Drug Administration intends to publish regulations that will govern nutrient additions. These regulations will include nutritional quality guidelines for specific classes of foods and standards of identity. Also governing nutrient additions are the regulations dealing with special dietary foods (1 CFR 125.1–125.3) and a standard of identity for dietary supplements of vitamins and minerals (21 CFR 80.1), published elsewhere in this issue of the FEDERAL REGISTER. Until the new regulations dealing with fortification become effective, the Food and Drug Administration will conduct frequent reviews of label practices of food manufacturers to prevent inappropriate and irrational addition of nutrients. Unwarranted claims or emphasis based on fortification constitute misbranding in violation of section 403(a) of the act.

Some foods currently available to consumers have added nutrients at levels of 50 percent or more of the U.S. RDA per serving and are promoted as a form of dietary supplement. The Commissioner has concluded that such products are dietary supplements of vitamins and minerals. Thus, if vitamins and/or minerals are added to a food so that a single serving provides 50 percent or more of the U.S. RDA of any one of the added vitamins and/or minerals, unless such addition is permitted or required in other regulations, e.g., standards of identity or nutritional quality guidelines, such food is a dietary supplement that is subject to and must conform to the standard of identity set forth in 21 CFR 80.1 as related to vitamins and minerals, as well as conforming to the requirements of nutrition labeling relating to nutrients other than vitamins and minerals.

With the selection of smaller increments (2 percent) below the 10 percent level, there is concern that claims of nutrient superiority of one food over another based solely on small differences could become a problem. The smaller in-

crements were selected in order to provide more useful nutrition labeling for consumers, because otherwise the cumulative amounts of low nutrient levels would not be known (e.g., it is estimated that 20 percent to 40 percent of the daily nutrient supply is obtained from foods containing less than 5 percent of the U.S. RDA in a serving); the small increments are not intended to suggest that a 2 percent or 5 percent difference in one food is itself significant. When making claims of nutrient superiority of one food over another, a difference of less than 10 percent of the U.S. RDA is not considered significant. Thus, any label claims for nutritional superiority, or claims that a product makes a significant contribution to the daily allowances of a nutrient(s), will be evaluated by this 10 percent standard.

Comments were received calling attention to the possible abuse of nutrition labeling by the use of labeling claims for specific properties of a food in the prevention or treatment of diseases or disorders, or suggesting that conventional foods in the U.S. diet, as usually prepared, are inadequate to meet nutritional needs or that "natural" sources of vitamins are different and better than vitamins chemically produced or in isolated form. These problems were also pointed out during the 1968–70 Special Dietary Hearings as reflected in the findings of fact and conclusions of law in 21 CFR Part 125 published elsewhere in this issue of the FEDERAL REGISTER. Based upon the foregoing, the Commissioner concludes that a food labeled under the provisions of this section shall not be considered to be in conformity with the requirements of sections 201(n) and 403(a) of the act if its labeling represents, suggests, or implies:

1. That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom.

2. That a diet of ordinary foods cannot supply adequate amounts of nutrients.

3. That the lack of optimum nutritive quality of a food, by reason of the soil on which that food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

4. That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of diets.

5. That the food has dietary properties when such properties are of no significant value or need in human nutrition. Over the years there have been a number of ingredients or products marketed as nutrients and nutritional supplements which have not been shown to be essential in human nutrition. This point was discussed in considerable detail during the 1968–70 Special Dietary Food Hearings. Among ingredients or products of this type are rutin, other bioflavonoids, para-aminobenzoic acid, inositol, and similar ingredients or products. These ingredients or products have frequently been combined with vitamins and minerals or otherwise represented as a type of nutritional supplement. In these situations, there is a false representation that these ingredients or products have nutritional value. The Commissioner has concluded that for ingredients or products of this type there may not properly be made direct or implied nutritional claims, and that in no instances can these ingredients or products be represented in any way that suggests a nutritional value. Combining these ingredients or products with added vitamins and/or minerals in any food, or adding these ingredients to any food for which nutrition labeling is used, or calling attention to these ingredients or products in a manner which would be considered to imply some nutritional benefit, is inherently misleading. Labeling of such ingredients or products may not state that their usefulness in human nutrition has not been established or otherwise disclaim dietary or therapeutic value since such statements are also misleading. The Commissioner recognizes that there are individuals who desire to purchase ingredients or products of this type for various reasons. These individuals have a right to obtain these ingredients or products as long as they are truthfully labeled. Thus, ingredients or products of this type may properly be marketed as individual ingredients or products or mixtures thereof, provided that no nutritional or dietary supplement claims or disclaimers are made.

6. That a natural vitamin in a food is superior to an added vitamin, or to differentiate in any way between vitamins naturally present from those added.

Protein quality. Wide divergence of opinions and views appears regarding the need to have a measure of protein quality. Suggestions for rating protein quality ranged from comprehensive scaling factors to simple delineation of vegetable and animal protein sources. Measures of protein quality are complex and expensive and commonly are related to use of the given protein as a unique source during the test. Despite the difficulty of selecting a standard, consumers should be protected against indiscriminate use of various low-quality sources of protein.

The 65-gram figure cited in the proposal is the value listed in the NAS–NRC report, "Recommended Dietary Allowances," 1968. This figure presumes consumption of a mixture of protein sources, and is therefore a reasonable value for proteins in general. The above report further lists 45.5 grams of "ideal" protein as the RDA. For this reason, 45.5 grams, or the integral value of 45 grams, is a reasonable figure for high-quality protein.

Extensive subdivision of protein types or qualities does not appear justified at this time in view of the current state of scientific knowledge in this area. The common measure of the quality of all the protein in a food is the Protein Efficiency Ratio (PER), an expensive and time-consuming biological feeding study that uses test animals. This is not an ideal measure for this purpose, even though it is the best currently available. A simplified approach to the designation of protein quality has therefore been devised.

A value of 45 grams of total protein has been selected as the U.S. RDA for protein having a PER value equal to or greater than that of casein. A value of 65 grams of total protein has been selected as the U.S. RDA for protein having a PER value less than that of casein. This gross separation of protein types reduces the need for extensive PER determinations. Total protein having a PER value less than 20 percent of the PER of casein shall not be stated on the label in terms of percent U.S. RDA, and shall be designated as "not a significant source of protein." This approach will be revised if further research provides a better answer to this difficult problem.

Compliance levels. The setting of practical limits of variation in nutrient levels for compliance purposes was the subject of extensive comments by some trade associations and manufacturers. Some 26 manufacturers and 16 trade associations opposed the compliance limits as listed in the proposal. However, none suggested a viable alternative. A few consumer groups and professionals spoke directly to this point; they were in favor of tighter compliance limits than those proposed. These views illustrate the complicated and interrelated problems involved in setting compliance limits for nutrition labeling.

The Commissioner is aware that there is natural variation in the nutrient content of food products. In developing a nutrition labeling system, it is therefore important that the manufacturer be permitted a sufficient tolerance so that he may provide useful nutrition information on the label without incurring excessive control costs, which would result in a significant price increase to the consumer. However, consumers have a right to expect that nutrition labeling honestly represent the products they buy. The change from the proposed label increments of 5 percent to increments of 2 percent permits more accurate representation of nutrient levels and increases the necessity of a compliance mechanism. This regulation has as its objective assuring compliance with requirements for average nutrient levels for units in a lot, with only as much variability among individual units as is inherent in the nutrients when foods are processed under good manufacturing practices.

The Commissioner realizes that manufacturers can exert varying degrees of control over the nutrient content of food products. Considerable control can be exerted over the nutrient levels when individual nutrients are added as specific substances. When discrete nutrients consisting of vitamins, minerals, and/or protein are added for the purposes of increasing the nutrient claims as a percent of the U.S. RDA, it is reasonable to require that compliance procedures be rigid. The compliance procedures set forth below for foods to which nutrients are so added require relatively exact nutrient levels in relation to label claims. Less variation in nutrient level is expected in a nutrient that is added to a

food than in a naturally occurring (indigenous) nutrient in a food. When any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food it is not considered an addition for purposes of classification and such food shall be evaluated for compliance purposes in terms of naturally occurring (indigenous) nutrients unless the same nutrient is also added.

Therefore, nutrients in foods will be divided generally into two classes for compliance purposes. These two classes are:

Class I. Added nutrients in fortified or fabricated foods.

Class II. Naturally occurring (indigenous) nutrients.

If a vitamin, mineral, or protein, or an ingredient containing such an added nutrient, is added to a food, the total amount of each such nutrient in the final food product is subject to Class I requirements with certain exceptions.

For either Class I or Class II nutrients, the compliance procedures must be applied to a definitive grouping of product units. Depending on the outcome of the compliance evaluation by the Food and Drug Administration, this grouping will either be considered as correctly labeled and therefore satisfactory for retail sale, or as mislabeled and subject to a regulatory action. Conventionally, such a grouping is a convenient collection of primary containers or units of the same size, type, and style, produced under conditions as nearly uniform as possible, e.g., production from a single shift or day, and designated by a common container code or marking. A collection of products defined in this way is termed a "lot" and is the basic unit to which the compliance procedures shall be applied.

Complete assurance that a lot is or is not in compliance with the labeled nutrient values would of course require destructive analysis of the entire lot. Therefore, a statistical approach involving analysis of a representative sample from the lot is required. Any such approach entailing examination of only a portion of the lot is subject to the possibility of an incorrect compliance decision. However, the differentiation between Class I and Class II nutrients, linked to a valid sampling plan, permits the derivation of a logical compliance procedure, which reduces the chance of an incorrect decision to a tolerable level.

In order to select a representative sample from a lot, the sampling must be accomplished while the lot is still reasonably intact. At the same time, the concern in nutrition labeling is that the label accurately reflect the nutrient level available to the consumer at the point of purchase. Both of these objectives will be satisfied by sampling the product at the manufacturer, wholesaler, or chain store warehouse.

Sample units are customarily combined to form a composite for nutrient analysis. Therefore, compliance procedures will be based on composite analysis. Such a composite must be formed from 12 consumer units chosen in a random fashion so as to be representative of the lot. The composites will be analyzed by the Association of Official Analytical Chemists (A.O.A.C.) methods where available or by appropriate analytical procedures the agency considers reliable.

The agency is prepared to provide guidance to manufacturers in relation to analytical procedures which will be used by the agency for compliance. For those cases in which an A.O.A.C. method is not available for a labeled nutrient, alternative methods of analysis may be submitted to the Food and Drug Administration to determine their acceptability.

In order to assure that the average nutrient level of a lot meets the label declaration for that nutrient, according to statistical projection, the following criteria shall be met:

Class I. The nutrient content of the composite shall be at least equal to the value for that nutrient declared on the label.

Class II. The nutrient content of the composite shall equal at least 80 percent of the value for that nutrient declared on the label.

Although the greater variability of Class II nutrients requires a different statistical approach, the average nutrient content of the lot will nonetheless be the same as for a Class I nutrient.

The above minimum composite values, together with suitable measures of variation among individual units in a lot, are sufficient to describe the compliance limits statistically, and to protect both the consumer and the manufacturer. The degree of flexibility permitted for composites in the case of Class II nutrients reflects both the degree of fluctuation in nutrient levels and the present lack of sufficient detailed data on nutrient variability. As data are accumulated through experience with nutrition labeling, it is anticipated that a lesser degree of flexibility may be needed.

The effectiveness of this compliance approach stems from the following considerations. Lots with different average nutrient levels will yield composites with different nutrient values. However, even for lots with the same average nutrient level, different composite values will result. Some composite values will be less than, some equal to, and some greater than the average nutrient level in the lot depending on the nutrient contents of the individual containers composited. Therefore, the actual composite value obtained depends not only on the average lot nutrient level but also on the variation in nutrient contents among individual containers in the lot. In general, the higher the lot average the higher the composite value, and the less variation among individual containers the closer the composite values will be to the lot average. The flexibility noted above for Class II nutrients reflects this dependence on variability.

With these compliance procedures, the chance of a lot being considered acceptable depends not only on the average nutrient level of individual units in the lot but also on their variability with respect to the average. It is assumed that Class I nutrient levels in individual containers will vary in such a way that they will have a standard deviation no larger than 10 percent of the lot average, and that Class II nutrients will have a standard deviation no larger than 25 percent of the lot average. For these variability assumptions, the stated compliance procedures will assure maintenance of average nutrient levels in the lot at or slightly above the label values. At the same time, these compliance procedures will provide reasonable protection against appreciable numbers of individual containers having nutrient levels below the label values. At the assumed level of variability in nutrient levels, the above compliance procedures afford reasonable protection to both producer and consumer.

The above discussion presumes that excesses of nutrients over labeled amounts in accord with good manufacturing practices are acceptable. However, many consumers are particularly interested in the caloric or fat content of foods for purposes of control of caloric or fat intake. The compliance methods that apply to other nutrients are therefore also made applicable to labeled caloric or fat values, with the composite sample values being required to be no more than 20 percent above the value appearing in the label.

The compliance procedures cited have been statistically evaluated and judged to be adequate. Additional information in this regard may be obtained from the Food and Drug Administration statistical staff. Should additional information become available that justifies any change in these compliance provisions, the provisions will be amended.

Representative values. Some 22 companies and 21 trade associations felt that "representative" values based upon averages of surveys made over the years, rather than actual analytical values based on current testing of lots of the manufacturer's product, should be permitted as a basis for labeling for many foods. The consumer groups generally favored use of current analytical values.

The Commissioner is aware of current efforts of the U.S. Department of Agriculture and industry to provide data and programing for a nutrient-data bank. The Food and Drug Administration applauds these efforts and encourages the groups involved to submit for such a bank data which will provide valuable information for industry, consumers, and governmental agencies. At the present time, however, the data available from survey averages are incomplete, and thus unsuitable as a basis for labeling claims. Moreover, processes of various manufacturers differ enough that comprehensive data may never provide a single representative "industry average" for processed foods. The consumer has a right to expect that nutrition labeling will honestly represent the food in the package. It is therefore essential that "representative" data be checked at this time by analysis of sufficient individual lots to give assurance that the labeled value adequately represents the product offered, at least until accurate and complete data are available on an industry-wide, regional, and manufacturer basis.

Comprehensive data obtained over a period of time for an individual product will undoubtedly yield more information on nutrient variability, and thus provide greater certainty with fewer product analyses. Proper statistical sampling by a manufacturer can also reduce the number of analyses to provide the required level of certainty.

Raw agricultural commodities. Some trade associations state that raw agricultural commodities, and particularly fresh fruits and vegetables, cannot be accurately labeled from a nutritional standpoint. They emphasize the natural variation of nutrients in various types of produce due to climate, species, growing conditions, and other factors.

The Commissioner is aware that certain of the problems inherent in nutrition labeling are increased in fresh fruits and vegetables. The answer to these problems lies not in exempting these products from nutrition labeling or in permitting inaccurate labeling, but in obtaining the information necessary for complete and accurate nutrition labeling.

For the reasons already given above, "representative" data for these products from handbooks and literature references do not presently provide an adequate basis for labeling. It is essential to establish accurate and complete analytical values for each product, and perhaps for each variety in each region. There is a steady increase in valid nutrient composition data on raw and fresh foods from State departments of agriculture, industry, universities, and Federal laboratories. The Commissioner believes that promulgation of this regulation will encourage such research, since the data obtained will serve as the basis for the expansion of nutrition labeling for fresh produce.

Serving size. Eighteen consumer groups and some professionals recommended that the Food and Drug Administration establish standard serving sizes. Some 13 manufacturers and five trade associations also requested such standardization. Standardization of serving sizes for foods requires close coordination of consumer representatives and members of the particular industry involved. Use of an overly large serving gives an inflated idea of nutrient content, but reduces the number of servings per package. The advent of nutrition labeling thus provides additional incentive for proper standardization of serving sizes. The term "serving" means that reasonable quantity of food suited for or practicable of consumption as part of a meal by an adult male engaged in light physical activity. A label statement regarding a serving shall be in terms of a convenient unit of such food or a convenient unit of measure that can be easily identified as an average or usual serving and can be readily understood by purchasers of such food (e.g., a serving may be expressed in slices, cookies, or wafers; or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls). A teaspoonful shall be considered to mean 5 milliliters (approximately ⅙ fluid oz.) in volume; a tablespoonful shall be considered to mean 15 milliliters (approximately ½ fluid oz.) in volume; and a cupful shall be considered to mean 240 milliliters (approximately 8 fluid oz.) in volume. Where there are no established reasonable standard serving sizes, the Commissioner intends to develop a procedure for establishing such reasonable standard serving sizes.

The Commissioner has therefore concluded, on the basis of currently available information, that nutrition labeling shall be based on the following general criteria:

1. Vitamins and minerals shall be expressed as a percentage of the U.S. Recommended Daily Allowances (U.S. RDA).

2. The nutrient content shall be related to a serving of the food expressed in common household terms or easily identifiable units.

3. The labeling shall indicate the caloric content and the amounts (in grams) of protein, carbohydrate, and fat in the product.

4. A complete listing of the seven commonly analyzed vitamins and minerals shall appear on the label of the product in a standard format, unless a food contains less than 2 percent of the U.S. RDA for each of four or more of the seven nutrients, in which case the manufacturer may choose to list only those nutrients present at 2 percent or more of the U.S. RDA with appropriate disclaimer for the nutrients not listed.

5. A listing of protein content shall appear on all products unless the product contains no substantial amount of protein. A method has been devised to protect the consumer against misrepresentation of low-quality proteins.

6. Nutrition information provided for by other regulations shall also appear in the same single panel on the label.

It is recognized that experience under this approach, as well as new information, may lead to desirable modifications. The Commissioner will review the regulation periodically, on his own initiative and at the request of others, and will propose and adopt whatever changes are shown to be in the public interest.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047, 1055; 21 U.S.C. 321, 343, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner hereby adds the following new section to Part 1 of title 21:

§ 1.17 Food; nutrition labeling.

(a) Nutrition information relating to food may be included on the label and in the labeling of a product: *Provided,* That it conforms to the requirements of this section. Except as provided in paragraph (h) of this section, inclusion of any added nutrient in a product or of any nutrition claim or information, other than sodium and/or cholesterol content, on a label or in advertising for a food subjects the label to the requirements of this section, and in labeling for a food subjects the label and that labeling to the requirements of this section except that the label of a food will not be subject to the requirements of this section solely because of a manufacturer's or distributor's direct written reply to an unsolicited request for information on cholesterol or fatty acid content of such a food. If vitamins and/or minerals are added to a food so that a single serving provides 50 percent or more of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age, as specified in § 125.1 of this chapter, of any one of the added vitamins and/or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner, the food shall conform to the standard of identity set forth in § 80.1 (21 CFR 80.1), but shall also conform to the labeling established in § 80.1, except that the labeling established in pargaraph (c) of this section, including the order for listing vitamins and minerals established in paragraph (c)(7)(iv), shall be used in lieu of the labeling established in 21 CFR 80.1(i)(1).

(b) All nutrient quantities (including vitamins, minerals, calories, protein, carbohydrate, and fat) shall be declared in relation to the average or usual serving. The term "serving" means that reasonable quantity of food suited for or practicable of consumption as part of a meal by an adult male engaged in light physical activity, or by an infant or child under 4 years of age when the article purports or is represented to be for consumption by an infant or child under 4 years of age. A label statement regarding a serving shall be in terms of a convenient unit of such food or a convenient unit of measure that can be easily identified as an average or usual serving and can be readily understood by purchasers of such food (e.g., a serving may be expressed in slices, cookies, or wafers; or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls). A teaspoonful shall be considered to mean 5 milliliters (approximately ⅙ fluid oz.) in volume; a tablespoonful shall be considered to mean 15 milliliters (approximately ½ fluid oz.) in volume; and a cupful shall be considered to mean 240 milliliters approximately 8 fluid oz.) in volume. The weight of the serving may also be expressed in grams.

(c) The declaration of nutrition information on the label and in labeling shall contain the following information in the following order, using the headings specified, under the overall heading of "Nutrition Information":

(1) "Serving size": A statement of the serving size.

(2) "Servings per container": The number of servings per container.

(3) "Caloric content": A statement of the caloric content per serving, expressed to the nearest 10-calorie increment. Caloric content shall be determined by the Atwater method as described in A. L. Merrill and B. K. Watt, "Energy Value

of Foods—Basis and Derivation", USDA Handbook 74 (1955).[1]

(4) "Protein content": A statement of the number of grams of protein in a serving expressed to the nearest gram.

(5) "Carbohydrate content": A statement of the number of grams of carbohydrate in a serving, expressed to the nearest gram.

(6) "Fat content": A statement of the number of grams of fat in a serving, expressed to the nearest gram. Fatty acid composition, cholesterol content, and sodium content may also be declared in compliance with §§ 1.18 and 125.9 of this chapter.

(i) When fatty acid composition is declared, the information on fatty acids required by § 1.18 shall be placed on the label immediately adjacent to the statement of fat content. The declaratory information statement required by § 1.18 (e) shall be placed either immediately following the statement on fat and fatty acids or shall be appropriately referenced by symbol and placed immediately following the completed nutrition information statement.

(ii) When cholesterol content is declared, the information on cholesterol required by § 1.18(c) shall immediately follow the statement on fat content (and fatty acids, if stated). The declaratory information statement required by § 1.18 (i) shall be placed either immediately following the statement on cholesterol or shall be appropriately referenced by symbol and placed immediately following the completed nutrition information statement.

(iii) When both fatty acid and cholesterol information are provided, the declaratory information statement may be combined as permitted by § 1.18(i).

(iv) When sodium is declared, the information on sodium required by § 125.9 of this chapter shall be placed on the label immediately following the statement on fat content (and fatty acid and/or cholesterol, if stated).

(7) "Percentage of U.S. Recommended Daily Allowances of protein, vitamins, and minerals": A statement of the amount per serving of the protein, vitamins, and minerals, as described in this subparagraph, expressed in percentage of the U.S. Recommended Daily Allowance (U.S. RDA).

(i) The percentages shall be expressed in 10 percent increments, except that 2 percent increments shall be used up to and including the 10 percent level, 5 percent increments above 10 percent and up to and including the 50 percent level, and 10 percent increments above the 50 percent level. Nutrients present in amounts less than 2 percent of the U.S. RDA may be indicated by a zero, or by an asterisk referring to another asterisk placed at the bottom of the table and followed by the statement "contains less than 2 percent of the U.S. RDA of this (these) nutrients (nutrients)." However, when a product contains less than 2 percent of the U.S. RDA for each of four or more of the seven nutrients specified in paragraph (c)(7)(iii) of this section, the manufacturer or distributor may choose to declare no more than three of those nutrients and none of the remainder listed in paragraph (c)(7)(iv) of this section. The statement "contains less than 2 percent of the U.S. RDA of _____", listing whichever of the seven nutrients are present at less than 2 percent of the U.S. RDA and have not been declared, shall directly follow the declared nutrients in the same type size. Any nurtient declared shall always appear in the order established in paragraph (c)(7)(iv) of this section.

(ii) The declaration of protein, which shall come first, shall be a statement of the amount per serving of protein, expressed as a percentage of the U.S. Recommended Daily Allowance (U.S. RDA).

(*a*) The U.S. RDA of the protein in a food product is 45 grams if the Protein Efficiency Ratio (PER) of the total protein in the product is equal to or greater than that of casein, and 65 grams if the PER of the total protein in the product is less than that of casein. The percentage of the U.S. RDA shall be declared as described in paragraph (c)(7)(i) of this section.

(*b*) Total protein with a PER less than 20 percent of the PER of casein may not be stated on the label in terms of percentage U.S. RDA, and the statement of protein content in grams per serving under paragraph (c)(4) of this section shall be modified by the statement "not a significant source of protein" immediately adjacent to the protein content statement regardless of the actual amount of protein present.

(iii) The declaration of vitamins and minerals, which shall follow the protein declaration, shall include vitamin A, vitamin C, thiamine, riboflavin, niacin, calcium, and iron, in that order, and may include any of the other vitamins and minerals listed in paragraph (c)(7)(iv) of this section in the order listed therein.

(iv) The following U.S. Recommended Daily Allowances (U.S. RDA) and nomenclature are established for these vitamins and minerals, essential in human nutrition:

Vitamin A, 5,000 International Units.
Vitamin C, 60 milligrams.[1]
Thiamine, 1.5 milligrams.[1]
Riboflavin, 1.7 milligrams.[1]
Niacin, 20 milligrams.
Calcium, 1.0 gram.
Iron, 18 milligrams.
Vitamin D, 400 International Units.
Vitamin E, 30 International Units.
Vitamin B_6, 2.0 milligrams.
Folic acid, 0.4 milligram.[1]
Vitamin B_{12}, 6 micrograms.
Phosphorus, 1.0 gram.
Iodine, 150 micrograms.
Magnesium, 400 milligrams.
Zinc, 15 milligrams.
Copper, 2 milligrams.
Biotin, 0.3 milligram.
Pantothenic acid, 10 milligrams.

These nutrients and levels have been derived by the Food and Drug Administration from the "Recommended Dietary Allowances," published by the Food and Nutrition Board, National Academy of Sciences-National Research Council, and are subject to amendment from time to time as more information on human nutrition becomes available.

(v) No claim may be made that a food is a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10 percent of the U.S. RDA in a serving. No claim may be made that a food is nutritionally superior to another food unless it contains at least 10 percent more of the U.S. RDA of the claimed nutrient per serving.

(d) Products with separately packaged ingredients or to which other ingredients are added by the user may be labeled as follows:

(1) If a product is comprised of two or more separately packaged ingredients enclosed in an outer container, nutrition labeling of the total product shall be located on the outer container to provide information for the consumer at the point of purchase. However, when two or more food products are simply combined together in such a manner that no outer container is used, or no outer label is available, each product shall have its own nutrition information statement, e.g., two boxes taped together or two cans combined in a clear plastic overwrap.

(2) If a food is commonly combined with another ingredient(s) before eating and directions for such combination are provided, a second column of figures may be used to provide a list of the nutrient contents for the final combination (e.g., a dry ready-to-eat cereal may be described with one set of percentage U.S. RDA values for the cereal as sold (per ounce), and another set for the cereal and milk as suggested in the label (per ounce of cereal and ½ cup of vitamin D fortified whole milk); and a cake mix may be labeled with one set of percentage U.S. RDA values for the dry mix (per serving), and another set for a serving of the final cake when prepared). The type and quantity of the other ingredient(s) to be added by the user to the product shall be specified.

(e) Compliance with this section shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a "lot".

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken one from each of 12 different randomly chosen shipping cases, to be representative of a lot. Composites shall be analyzed by Association of Official Analytical Chemists (A.O.A.C.) methods where

[1] Copies may be obtained from: Division of Nutrition (BF-124), Bureau of Foods, Food and Drug Administration, 200 C Street SW., Washington, DC 20204.

[1] The following synonyms may be added in parentheses immediately following the name of the vitamin:

Vitamin	*Synonym*
Vitamin C	Ascorbic acid.
Folic acid	Folacin.
Riboflavin	Vitamin B_2.
Thiamine	Vitamin B_1.

available, or, if no A.O.A.C method is available, by reliable and appropriate analytical procedures. Methods of analysis may be submitted to the Food and Drug Administration to determine their acceptability.

(3) Two classes of nutrients are defined for purposes of compliance:

Class I. Added nutrients in fortified or fabricated foods.
Class II. Naturally occurring (indigenous) nutrients.

If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added

(4) A food with a label declaration of a vitamin, mineral, or protein shall be deemed to be misbranded under section 403(a) of the act unless it meets the following requirements:

(i) *Class I vitamin, mineral, or protein.* The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) *Class II vitamin, mineral, or protein.* The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label.

(5) A food with a label declaration of calories, carbohydrate, or fat shall be deemed to be misbranded under section 403(a) of the act unless the nutrient content of the composite is no greater than 20 percent in excess of the value for that nutrient declared on the label.

(6) Reasonable excesses of a vitamin, mineral, or protein over labeled amounts are acceptable within good manufacturing practices. Reasonable deficiencies of calories or fat under labeled amounts are acceptable within good manufacturing practices.

(f) A statement may be included on the label or in labeling offering additional nutrition information upon written request to a specified address. Any additional labeling furnished to consumers or professionals shall comply with all applicable requirements of this chapter.

(g) The location of nutrition information on a label shall be in compliance with § 1.8d.

(h) The following foods are exempt from this section or are subject to special labeling requirements:

(1) Except where expressly covered by § 125.5 of this chapter, infant, baby, and junior-type foods marketed and promoted for children under 4 years of age shall be labeled in compliance with this section except that the term "serving" shall mean that reasonable quantity of food suited for or practicable of consumption by an infant or child under 4 years of age and that the U.S. RDA levels for infants and children under 4 years of age contained in § 125.1(b) shall be used in lieu of the U.S. RDA levels contained in paragraph (c)(7)(iv) of this section.

(2) Dietary supplements, the nutrients of which consist solely of vitamins and/or minerals, shall be labeled in compliance with §§ 80.1 and 125.3 of this chapter, except that the labeling of a dietary supplement in food form, e.g., a breakfast cereal, shall conform to the labeling established in paragraph (c) of this section, including the order for listing vitamins and minerals established in paragraph (c)(7)(iv) of this section, in lieu of the labeling established in § 80.1(i)(1).

(3) Any food represented for use as the sole item of the diet shall be labeled in compliance with Part 125 of this chapter.

(4) Foods represented for use solely under medical supervision in the dietary management of specific diseases and disorders shall be labeled in compliance with Part 125 of this chapter.

(5) Iodized salt shall be labeled in compliance with § 3.87 of this chapter.

(6) A nutrient(s) included in food solely for technological purposes may be declared solely in the ingredient statement, without complying with this section, if the nutrient(s) is otherwise not referred to on the label or in labeling or in advertising.

(7) A standardized food containing an added nutrient(s), e.g., enriched flour, and included in another food as a component may be declared in the ingredient statement by its standardized name, without compliance with this section, if neither the nutrient(s) nor the component is otherwise referred to on the label or in labeling or in advertising.

(i) A food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its labeling represents, suggests, or implies:

(1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom.

(2) That a diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) That the lack of optimum nutritive quality of a food, by reason of the soil on which that food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of diets.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition. Ingredients or products such as rutin, other bioflavonoids, para-aminobenzoic acid, inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential in human nutrition may not be combined with vitamins and/or minerals, added to food labeled in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof provided that the possibility of nutritional, dietary, or therapeutic value is not stated or implied (e.g., their labeling does not state that their usefulness in human nutrition has not been established and does not otherwise disclaim nutritional, dietary, or therapeutic value).

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin, or to differentiate in any way between vitamins naturally present from those added.

Effective date. All labeling ordered after December 31, 1973, and all labeling used for products shipped in interstate commerce after December 31, 1974, shall comply with this regulation.

(Secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047, 1055; 21 U.S.C. 321, 343, 371(a))

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

NOTE: Incorporation by reference provisions approved by the Director of the Federal Register, January 15, 1973.

[FR Doc.73-988 Filed 1-18-73;8:45 am]

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

Labeling of Foods With Information on Cholesterol and Fat and Fatty Acid Composition

In the FEDERAL REGISTER of June 15, 1971 (36 FR 11521), the Commissioner of Food and Drugs proposed a series of three proposals relating to labeling of foods with information on cholesterol, fat, and fatty acid composition.

The first proposal concerned a proposed statement of policy on ingredient statements regarding fats and oils in food for human consumption. This proposal is still under consideration.

The second proposal was that there be an amendment to § 3.41 (21 CFR 3.41), the statement of policy on the status under the Federal Food, Drug, and Cosmetic Act of articles offered to the general public for the control or reduction of blood cholesterol levels and for the prevention and treatment of heart and artery disease. It was proposed that there be added to this statement of policy two new paragraphs (d) and (e) which would declare misleading under the act, any statement in the labeling which represents or suggests that the article contains less or no cholesterol and for any use of the terms "polyunsaturated," "monounsaturated," or "saturated" in relation to the fat content of foods except when expressly stated in accordance with 21 CFR 125.12 as proposed in the same issue of the FEDERAL REGISTER.

The third proposal was a new regulation (21 CFR 125.12) on the requirements for label statements relating to oils, fats, and fatty acids used as a means of regulating intake of fatty acids. This proposal established labeling requirements for foods represented for special

dietary use containing 10 percent or more fat on a dry weight basis and no less than 3 grams of fat in an average serving.

Ninety days were originally provided for filing of comments on these proposals; this comment period was extended to November 12, 1971, by notices published in the FEDERAL REGISTER of September 9, 1971 (36 FR 18098).

The Commissioner received 502 letters commenting on one or more of the proposals that were published simultaneously on June 15, 1971 (36 FR 11521).

The Commissioner has carefully reviewed the comments concerning the labeling of cholesterol, fat, and fatty acids, and has concluded that these two issues should be considered in a uniform manner as both deal with the consumers' need to have informative labeling on foods which make up the usual diet of those individuals on modified diets on the advice of their physician. In the opinion of the Commissioner such labeling would markedly assist individuals in their attempts to adhere to a modified diet. Thus, the two proposals published as an amendment to 21 CFR 3.41 and as a proposed new section (21 CFR 125.12) have been combined into a single new regulation (21 CFR 1.18).

I. CHOLESTEROL LABELING

Many consumers expressed an interest in having cholesterol values given on all food labels. Individuals who asked that cholesterol values be allowed on food labels supported their view by saying they were on a low or moderate cholesterol diet on instruction of their physicians in an effort to reduce one of the risk factors, i.e., high blood cholesterol levels. They felt that unless foods are labeled with cholesterol content it would be difficult to follow their doctors' orders. Some respondents asserted that the Commissioner was making a less than objective appraisal of the current status or knowledge about the etiology of heart and artery disease by not changing paragraphs (a) and (b) of 21 CFR 3.41 which were factual in 1959 when the statements were made, but which do not now address the subject candidly.

Manufacturers and their spokesmen felt that labeling food with information about fatty acids as required under the proposed § 125.12 together with the application of the constraints of § 3.41 would prevent them from labeling general purpose foods with important composition information which, in the context of the scientific controversy over the etiology of heart and artery disease, may be important for some physicians, paramedical personnel, and patients. These respondents felt that cholesterol, food fat, and calorie composition information on food labels should not, by itself, constitute a representation that the food is for special dietary use.

Many respondents, viewing what they regarded as an apparent dichotomy between the recognition of the greater importance of fatty acid composition compared with the cholesterol composition of foods, felt that the Food and Drug Administration was not being objective and fair. They did not disagree with the position reflected in the proposed amendment to § 3.41 that in many instances it might be improper or frivolous to make label declarations of cholesterol content, but they argued that there does not appear to be a reasonable basis for prohibiting truthful label statements about cholesterol content while at the same time allowing the presence of label statements relating to fatty acid content.

The Commissioner has considered the question of cholesterol labeling of food in relation to the sources of cholesterol in the diet of Americans. The ordinary intake of cholesterol by adults in this country ranges from between 300 to 1,000 milligrams per day and is significantly affected by the cholesterol level of the particular foods chosen by the individual for his daily diet. The Commissioner believes that consumers who have been properly instructed by their physicians understand the physicians' requests that they curtail their intake of certain foods. All foods from vegetable sources and many fabricated foods which contain, as a minor ingredient, an item from a food with high cholesterol content, are not important contributors of cholesterol; however, this information itself may be useful label information for consumers if it is presented in a factual and nonmisleading manner.

The Commissioner recognizes that products can be specially manufactured or formulated to be in simulation of a food in one of the major cholesterol-contributing foods in such a way that these products contain either no cholesterol or significantly less cholesterol than their regular counterpart foods. The manufacturers of products of this kind believe that consumers will benefit from knowing the cholesterol content of these products. Consumers should not be misled, however, into believing that these products are equivalent to their regular counterpart foods in all important respects, especially nutritional, if they are not. The criterion, therefore, for labeling products of this kind should be that the product (analogue) be nutritionally equivalent to the food which it obviously simulates. When requested, the Food and Drug Administration will render opinions on the nutritional equivalency of new products as compared with conventional products. The Commissioner is publishing elsewhere in this issue of the FEDERAL REGISTER a proposed new § 1.8(e) governing the labeling of such substitute foods.

In light of all the available information, the Commissioner has concluded that new § 1.18 should include provisions regulating the labeling of cholesterol content. Labeling permitted by this new section may voluntarily be used by any manufacturer to show the cholesterol content of a food. The use of any claim or information concerning cholesterol on a label or in labeling or advertising for a food also subjects the label to the requirements of this section. The label statement shall provide the following information in the following order:

1. A statement of the serving size.

2. The number of milligrams of cholesterol per serving.

3. The number of milligrams of cholesterol per 100 grams of the food.

4. The statement "Information on cholesterol content is provided for individuals who, on the advice of a physician, wish to modify their total dietary intake of cholesterol."

This information on cholesterol content shall appear on the label in accordance with new § 1.8d, which is published elsewhere in this issue of the FEDERAL REGISTER. In order to avoid giving the information undue prominence, in no event may it appear on the labeling in more than the minimum type size required for the declarition of net quantity of contents by § 1.8b of this chapter.

If the food is labeled in compliance with § 1.17 (nutrition labeling), which is also published elsewhere in this issue of the FEDERAL REGISTER, and the manufacturer chooses to include the cholesterol content, the above information shall be included as provided in § 1.17(c)(6)(ii), except that the serving size need not be repeated. Section 1.17(a) specifically provides, however, that inclusion only of cholesterol content on a food label does not require full nutrition labeling in compliance with § 1.17.

II. FAT AND FATTY ACID LABELING

In relation to the proposal on the labeling of foods for fat and fatty acid, 229 comments were received from a number of sources. Consumers as a whole favored the proposal. Comments from the scientific community, trade associations, and manufacturers expressed reservations about specific portions of the proposal but indicated that these groups would accept a revised regulation that was reasonable and enforceable.

A suggested alternative to the proposed § 125.12 would move the requirements of the proposed §§ 125.12 to 3.41 (21 U.S.C. 3.41) by revising the proposed § 3.41(e). Under this alternative the label statements would not constitute representations for special dietary use, but would provide labeling in a meaningful and uniform way on fat and fatty acid composition regardless whether the product's composition is fixed by nature or formulated by the food technologist. There were a number of other comments, some in opposition to the proposal and others containing proposed alternative action of several types:

1. Leave label declaration as it is presently constituted.

2. Survey the U.S. population to see what the consumer really wants on a label.

3. Require a label disclaimer statement which would tell the consumer that the information on fat content does not represent the product for treatment or prevention of disease.

4. Liberalize criteria for labeling by lowering minimum values for amount of fat in foods.

5. State more clearly the definitions for polyunsaturated and saturated fatty acids, and for special dietary food.

6. Make provision for including the monosaturated fatty acid values on the label.

7. State clearly the conditions which influence whether the application of the section is optional or mandatory.

8. Withdraw proposal § 125.12.

9. Proposed regulation does not delineate the criteria for determining whether a fat is for special dietary use or for general use.

10. List any polyunsaturate not as the glyceryl ester but as P/S (polyunsaturated to saturated) ratio, e.g., P/S ratio of 2.5 or more.

11. Change term "glyceryl ester" to "glyceryl triester."

12. Provide for including the percentage of trans-fatty acid value on the label.

13. Make the regulation mandatory for all foods containing fats.

14. Establish the range of variation to be allowed in fatty acid composition information.

15. "Average serving" should be defined.

16. Canadian Food and Drug Directorate FA–59 method for cis-methylene-interrupted fatty acids is not reliable.

Each of these have been considered, and where applicable changes or modifications have been made in the proposal. They are included in the following discussion. However, in regard to the comments suggesting delay in action, the Commissioner is of the opinion that further delay on providing consumers with information on the fat and fatty acid content of foods would serve no purpose, and accordingly new § 1.18 provides for such labeling.

Some comments indicated that the correspondents wanted the provisions of the proposed section to be voluntary; others argued for mandatory labeling requirements. Some questions of clarity of language regarding voluntary use were asked. The use of labeling as provided by the final regulation shall be on a voluntary basis for all foods, and will be mandatory if claims are made with respect to fatty acid composition but not if claims are made with respect to general fat content. There are many general purpose foods that could be used for dietary regulation of fat and/or fatty acid intake, and there is no reason why the option to label these foods should not be exercised by a manufacturer, as long as he complies with the labeling requirements contained in new § 1.18 and does not make medical claims.

New § 1.17 (nutrition labeling) and new § 1.18 (fat and fatty acid labeling) are closely related. Section 1.17(c)(6) provides that nutrition labeling shall include the number of grams of fat per serving of a food. Any claim or information with respect to any nutrient covered by § 1.17, e.g., protein, fat, calories, vitamins, automatically requires full nutrition labeling under § 1.17. Thus, any claim or information relating to the fat content, e.g., the percentage of fat in the product, automatically makes § 1.17 applicable.

New § 1.18 (fat and fatty acid labeling) is far more narrow, and is applicable only when a claim or information is included on the label or in labeling or advertising specifically related to the fatty acid composition of a food. Thus, information about fat content does not make § 1.18 applicable unless that information includes a reference to fatty acid composition. When § 1.18 is applicable, on the other hand, the information required under its provisions with respect to fat and fatty acids automatically also makes § 1.17 applicable. Section 1.17(c)(6)(i) specifically provides for the inclusion of the labeling required by § 1.18 in the standard nutrition labeling format. In short, § 1.17 does not require labeling under § 1.18, but § 1.18 labeling automatically requires labeling under § 1.17 and must be included within the § 1.17 format.

While comments were received suggesting that the polyunsaturated fatty acid to saturated fatty acid ratio (P/S) be included on the label, the majority of comments stressed the current interest in actual amounts of fatty acids in the diet. For those desiring to determine the P/S ratio, the information required to be furnished by the regulation will be sufficient to enable the consumer to calculate it by dividing the amount in grams of polyunsaturated fatty acid by the amount in grams of saturated fatty acids.

Adverse comments were submitted relating to the proposed limiting of fatty acid labeling to foods containing a minimum of 10 percent total fat on a dry-matter basis and of 3 grams total fat per serving. A majority of comments were concerned with the 10-percent figure on a dry weight basis. Suggestions were made to change this to another value; some believed that it should be less than 3 percent, and others believed it should be more than 10 percent. Based upon an analysis of the foods which contribute fat to the diet, the Commissioner concludes that it is reasonable to limit fatty acid labeling to foods containing a minimum of 10 percent total fat on a dry matter basis. This will prevent manufacturers from placing fatty acid information on products which are insignificant sources of fatty acid in the diet.

One respondent suggested that the fat-per-serving figure should be lowered from 3 to 2 grams because the larger figure would exclude some foods such as coffee whiteners used in the daily diet of some individuals which affects their total fat intake. This change is reflected in the final order.

Considerable industrial and trade organization concern over the fatty acid categories or groups that should appear on the label was evident from the wide variety of comments and suggestions received. Several possible combinations of fatty acid categories or groups for label purposes emerged from the comments; these are:

1. Polyunsaturated fatty acids, monounsaturated fatty acids, saturated fatty acids (C–1 through C–22).

2. *Cis*-polyunsaturated fatty acids, *trans*-unsaturated fatty acids, monounsaturated fatty acids, saturated fatty acids (C–1 through C–22).

3. *Cis*-polyunsaturated fatty acids, *trans*-unsaturated fatty acids, conjugated polyunsaturated fatty acids, monounsaturated fatty acids, saturated fatty acids (C–1 through C–22).

4. Polyunsaturated fatty acids, monounsaturated fatty acids, saturated fatty acids (C–14 through C–22).

5. (Same as Categories 1 to 4 above except that saturated fatty acids would encompass C–12 through C–18).

6. *Cis*-polyunsaturated fatty acids, saturated fatty acids (C–12 through C–18), other fatty acids (total amount of fatty acids minus sum of amounts in first two categories).

All those who expressed an opinion concerning this matter felt that it would be informative to include the amount of polyunsaturated fatty acids present to be declared as one category. The other categories to be declared was the point of controversy.

In the comments received, reference was made to scientific reports which suggest that any fatty acid category may contain a quality or factor which tends to elevate blood cholesterol levels in controlled experiments. However, the most widely accepted opinion at this time is that long-chain saturated fatty acids and polyunsaturated fatty acids may have some relationship to changes in serum cholesterol levels. Most saturated fatty acids in conventional foods are long-chain fatty acids; they contain 12 carbons or more. Saturated fatty acids containing eight and 10 carbons (referred to as medium-chain fatty acids) and those containing four and seven carbons (referred to as short-chain fatty acids) are absorbed and utilized in a much different manner than are long-chain fatty acids. Their metabolic effects on plasma lipids and cholesterol appear to be different than those of the long-chain saturated fatty acids.

Since the label statements should be both suitably informative and simple to understand, approximately three categories is the limit that can be expected to be tolerated by consumers and industry alike. The classification outlined below will provide adequate useful information for persons on a fat-modified diet. In view of the fact that most people expect the sum of percentage values in a complete statement of total fatty acid content to be 100, it is appropriate to subtract from 100 the sum of the percentages of polyunsaturated and saturated fatty acids; the remainder being the third category "other fatty acids."

For the purpose of labeling, therefore, saturated fatty acids containing less than 12 carbons will not be considered in the category of "saturated fatty acids", but shall be included in the category "other fatty acids". Based on practicality, ability to carry out rapid analysis, and consequently the ability to enforce for regulation, the long-chain saturated fatty acid range of C–12 through C–18 (lauric, myristic, palmitic, and stearic acids) have been defined as "saturated fatty acids."

Several comments suggested that the *trans*-unsaturated fatty acids present in hydrogenated fats, and conjugated polyunsaturated fatty acids should be listed

on the labels. *Trans*-unsaturated fatty acids generally constitute a small portion of the total fatty acids in marketed fats and oils. This situation is similar to that of the conjugated polyunsaturated fatty acids, although very little information on the content of these two fatty acid subgroups in foods is available. Some fat and oil manufacturers do make periodic checks on the content of these subgroups in their products, but to require such monitoring by industry and government is unreasonable at this time. If new evidence suggests that it is necessary to require label information on either one or both of these subgroups, the appropriate section(s) of the regulations will be amended.

The original proposal on fatty acid labeling required the quantities of fatty acids to be listed as a percentage of the total fat content. Comments were received from nutritionists who advise patients on modifying their diet suggesting that the actual quantity in terms of grams of fat and fatty acids is more useful than percentages as this nomenclature is used in advising patients on the modification of fat and fatty acid content of their diet. Since the purpose of the fatty acid labeling is to assist those individuals seeking to modify the fat and fatty acid content of their diet and those professionals seeking to help these indviduals, it is reasonable to provide the fatty acid information in grams per serving.

The Commissioner has concluded that claims or information about fatty acid content should require inclusion on the label of the following fat and fatty acid information in addition to full nutrition labeling.

1. The amounts of fatty acids expressed in grams calculated as triglycerides, in the following three categories with the headings as listed, and in the following order:

(i) *cis, cis*-methylene-interrupted polyunsaturated fatty acids, stated as "Polyunsaturated fatty acids";

(ii) The sum of lauric, myristic, palmitic, and stearic acids, stated as "Saturated fatty acids"; and

(iii) The difference, stated as "Other fatty acids", between the total amount of fatty acids and the sum of fatty acids in (i) and (ii).

2. The total fat content in terms of the percent of the total calories provided by fat with the heading, Percent of calories from fat.

Several comments were received concerning the analytical methods and compliance procedures to be used in regulating products with fat and fatty acid, and/or cholesterol labeling. The Commissioner is aware that there is natural variation in the fat and cholesterol content of food products. In developing a labeling system it is therefore important that the manufacturer be permitted a tolerance so that he may provide useful information on the label without incurring excessive control costs, which will result in a significant price increase to the consumer. However, consumers have a right to expect that labeling honestly represents the products they buy.

Section 1.17, governing nutrition labeling, contains a detailed statistically valid compliance mechanism. Basically the same compliance provisions are included in this regulation for determining cholesterol, fat, and fatty acids as are included in new § 1.17 for determining fat. For the purposes of compliance a food with a label declaration of cholesterol content shall be deemed to be misbranded under section 403(a) of the Act if the content of a 12-sample composite is greater than 20 percent in excess of the value for the cholesterol content declared on the label. A food with a label declaration of fatty acids content shall be deemed to be misbranded under section 403(a) of the Act if the composite is greater than 20 percent in excess of the value or less than 80 percent of the value for the fatty acids declared on the label.

Comments on methods for analysis asked that the specific methods to be used for compliance be identified. The methods for fat, fatty acids, and cholesterol will be those of the Association of Official Analytical Chemists (AOAC), or other reliable and appropriate methods. Methods of analysis may be submitted to the Food and Drug Administration to determine their acceptability. The determination of *cis, cis*-methylene-interrupted polyunsaturated fatty acids of fats, and oils will be carried out by the Canadian Food and Drug Directorate FA–59 method entitled "Enzymatic Determination of Polyunsaturated Fatty" published during December 1967 as modified by the Division of Nutrition, Food and Drug Administration. The FA–59 method is a modification of the MacGee method (Analytical Chemistry 31, 298 [1959]).

The problem of defining the serving size was raised. Each manufacturer should define the serving size appropriate for his specific product and state the serving size on the label. Where there are no established reasonable standard serving sizes, or if there is an unreasonable variance among manufacturers, the Commissioner intends to develop a procedure for establishing such reasonable standard serving sizes.

For the purposes of this regulation, the same basic definitions shall apply as in §§ 1.17 and 125.1. An average serving shall be expressed in terms of a convenient unit of measure that can be readily understood and utilized by purchasers of such food. For example, a serving may be expressed in terms of slices, cookies, wafers, ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls. A teaspoonful shall be considered to mean 5 milliliters (approximately ⅙ fluid ounce) in volume; a tablespoonful shall be considered to mean 15 milliliters (approximately ½ fluid ounce) in volume; and a cupful shall be considered to mean 240 milliliters (approximately 8 fluid ounces) in volume.

It was pointed out in many comments that it would be in the best interest of consumers to have a declaratory statement that would appear in the labeling of products to accompany the information permitted in this section. Such statement would state to the purchaser that the product may be useful to those persons who are advised by a physician to modify their fat intake as part of a total dietary plan. There may be no statement or implication, however, that the product per se will be sufficient to modify fat intake, or will help to prevent coronary heart disease or its adjunctive conditions. This is reasonable in light of the fact that the Food and Drug Administration is neither recommending any dietary regimens nor taking a position in the dietary fat/coronary heart disease controversy. The regulation is being issued in response to public and medical requests that such information be placed on food product labels. The regulation is designed simply to provide fat and fatty acid label information that will be useful to consumers, physicians, dietitians, and other health professionals who are involved directly or indirectly in regulating an individual's dietary intake of total fat and/or fatty acids. Thus, the statement "Information on fat content is provided for individuals who, on the advice of a physician, are modifying their total dietary intake of fat" would immediately follow the required statements on fat and fatty acid content, as required in 21 CFR 1.17.

There was an oversight in the published proposal, in that it lacked any reference to the kind of information which must appear in product literature sent by the manufacturer on request of a consumer. Such material is labeling. In some cases, it is possible that a manufacturer may not have a product labeled with fat and fatty acid information, but will provide information about the product in labeling if the customer writes the company. A declaration of cholesterol or fatty acid content on the label or in advertising of a food subjects the label to the requirements of this section. A declaration of cholesterol or fatty acid content in labeling of a food subjects the label and that labeling to the requirements of this section except that the label of a food will not be subject to the requirements of this section solely because of a manufacturer's or distributor's direct written reply to an unsolicited request for information on cholesterol or fatty acid content of such food.

The cholesterol and fat and fatty acid labeling as set forth below incorporates the more useful principles presented in the comments received on the published proposal. The Commissioner has concluded in relation to the labeling of the cholesterol, fat, and fatty acid content of foods that:

1. A restatement of the policy regarding labeling of foods possibly of value in diets for the control of fatty acid and cholesterol consumption is appropriate.

2. Information associated with the cholesterol, fat, and fatty acid composition of foods should be combined in a single regulation as set forth below.

3. It is necessary to call consumers' attention, by means of a label statement, to the fact that information being

permitted by promulgation of this regulation should be used with the understanding that it is useful only when the total dietary intake of fat and/or cholesterol is being controlled and then only when this is done on the initial and continuing advice of a physician familiar with the patient's condition.

4. The cholesterol content should be allowed to be stated on the label of any food in succinct terms.

5. The fatty acid content should be allowed to be stated on the label of foods with at least 10 percent total fat on a dry weight basis and/or containing at least 2 grams of fat in a serving. When the manufacturer voluntarily elects to provide information under § 1.18 it is reasonable to require complete nutrition information as provided for in § 1.17 and in the format required by § 1.17(c)(6)(i).

6. When a manufacturer elects to declare cholesterol content it is reasonable not to require complete nutrition labeling. When a manufacturer elects to provide chlosterol and nutrition labeling on a product it is reasonable that the labeling be in compliance with 21 CFR 1.17(c)(6)(ii).

7. Statements of cholesterol and fat content, both by themselves and when accompanied by an informational statement indicated in conclusion 3 above, are not misleading; however, direct claims that a product will prevent, mitigate, or cure atherosclerotic cardiovascular disease or any attendant condition are false and misleading.

Accordingly, having considered the comments received and other relevant information, and after further study on the impact of his proposal on current medical practice, the Commissioner concludes that a new § 1.18 *Labeling of foods in relation to fat and fatty acid, and cholesterol content* should be established, combining the provisions of the existing and proposed § 3.41 and the proposed § 125.12 (36 FR 11521), to provide for more informative labeling of foods containing cholesterol and fat and fatty acids.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1047–1048 as amended, 1055; 21 U.S.C. 321, 343, 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 1 and 3 are amended as follows:

1. In Part 1 a new § 1.18 is added to read as follows:

§ 1.18 Labeling of foods in relation to fat and fatty acid, and cholesterol content.

(a) Implicit or explicit claims for the value of food in preventing or treating heart or artery disease can be misleading to consumers. However, a significant segment of the medical community is recommending that individuals modify their total diet by eliminating certain foods or by replacing certain foods with others in order to effect changes in the levels of blood components. Although there have been no definitive studies which have demonstrated beyond doubt that extensive changes in the consumption of fat and cholesterol by the general public are desirable, it is nevertheless appropriate to provide for informative labeling which will help individuals to identify foods for inclusion in fat-modified diets recommended by physicans. It is also appropriate to prohibit label statements which misrepresent specific foods as being, of themselves, of value in the control of the levels of these blood components or in the control of heart or artery disease.

(b) A label statement regarding a serving shall be expressed in terms of a convenient unit of measure that can be readily understood and utilized by purchasers of such food. For example, a serving may be expressed in terms of slices, cookies, wafers, ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls. A teaspoonful shall be considered to mean 5 milliliters (approximately one-sixth fluid ounce) in volume; a tablespoonful shall be considered to mean 15 milliliters (approximately one-half fluid ounce) in volume, and a cupful shall be considered to mean 240 milliliters (approximately 8 fluid ounces) in volume.

(c) A food label or labeling may include a statement of the cholesterol content of the food, provided that it is stated both in terms of the number of milligrams per serving and in terms of the number of milligrams per 100 grams of the food. This listing shall follow a statement of the serving size, which shall be determined in accordance with § 1.17 and shall appear as provided in § 1.8d, but in no case in a type size larger than the minimum type size required for the declaration of net quantity of contents by § 1.8b of this chapter. No other statement may be made relating to cholesterol. When the cholesterol content is stated on the label of a food which is also labeled in accordance with § 1.17, the statement of the cholesterol content shall conform to the requirements of § 1.17(c)(6)(ii).

(d) A food label or labeling may include information on the fatty acid content of the food: *Provided*, That it meets the following conditions.

(1) The food contains 10 percent or more fat on a dry weight basis and not less than 2 grams of fat in an average serving. Any food containing less than 10 percent total fat on a dry weight basis and/or containing less than 2 grams of fat in a serving is not suitable for use by man as a means of regulating the intake of fatty acids.

(2) The food is labeled in compliance with § 1.17 and the following information is included in the folowing order in accordance with § 1.17(c)(6)(ii).

(i) The amounts of fatty acids, calculated as the triglycerides, shall be stated in grams per serving in the following three categories, stated with the following headings, in the following order, and displayed in equal prominence:

(*a*) *cis, cis* - methylene - interrupted polyunsaturated fatty acids, stated as "Polyunsaturated fatty acids";

(*b*) The sum of lauric, myristic, palmitic, and steric acids, stated as "Saturated fatty acids"; and

(*c*) The difference, stated as other" fatty acids," between the total amount of fatty acids and the sum of fatty acids in paragraph (d)(1)(i) (*a*) and (*b*) of this section.

(ii) The total fat content in terms of the percentage of the total calories in the food, provided by fat with the heading "Percent of calories from fat:".

(iii) The statement required by paragraph (e) of this section.

(iv) No other statement may be made relating to fatty acid content.

(e) A food labeled in accordance with paragraph (c) or (d) of this section shall display the folowing statement on the label: "Information on fat (and/or cholesterol, where appropriate) content is provided for individuals who, on the advice of a physician, are modifying their total dietary intake of fat (and/or cholesterol, where appropriate.)" If the food is not labeled in accordance with § 1.17 and is labeled only in accordance with paragraph (c) of this section, the statement shall appear in the same label panel and in proximity to the statements prescribed in paragraph (c) of this section and in the same type size. In the event the cholesterol content is included under nutritional labeling, the statement shall be in compliance with § 1.17(c)(6)(ii).

(f) A declaration of cholesterol or fatty acid content on the label or in advertising of a food subjects the label to the requirements of this section. A declaration of cholesterol or fatty acid content in the labeling of a food subjects the label and that labeling to the requirements of this section except that the label of a food will not be subject to the requirements of this section solely because of a manufacturer's or distributor's direct written reply to an unsolicited request for information on cholesterol or fatty acid content of such food.

(g) Compliance with this section shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking constitutes a "lot."

(2) The sample for analysis shall consist of a composite of 12 subsamples (consumer units), taken one from each of 12 different randomly chosen shipping cases, to be representative of a lot.

(3) Composites shall be analyzed for fat and saturated fatty acids by the methods of the Association of Official Analytical Chemists (AOAC). The methods for fat, fatty acids, and cholesterol will be those of the Association of Official Analytical Chemists (AOAC), or other reliable and appropriate methods. Alternative methods of analysis

may be submitted to the Food and Drug Administration to determine their acceptability. The determination of cis, cis-methylene-interrupted polyunsaturated fatty acids will be the Canadian Food and Drug Directorate Method FA–59[1] for cis-methylene-interrupted fatty acid.

(4) A food with a label declaration of cholesterol content shall be deemed to be misbranded under section 403(a) of the Act if the content of the composite is greater than 20 percent in excess of the value for the cholesterol content declared on the label.

(5) A food with a label declaration of fat content shall be deemed to be misbranded under section 403(a) of the Act if the content of the composite is greater than 20 percent in excess of the value for the fat content declared on the label.

(6) A food with a label declaration of fatty acid content shall be deemed to be misbranded under section 403(a) of the Act if the content of the composite is greater than 20 percent in excess of the value, or less than 80 percent of the value, for the fatty acid content declared on the label.

(h) Label statements made in accordance with paragraphs (c), (d), or (e) of this section shall comply with the requirements of § 1.8d, but in no case may it be printed in larger than the minimum size type required for the declaration of net quantity of contents by § 1.8b.

(i) No label or labeling may contain a claim indicating, suggesting, or implying that the product will prevent, mitigate, or cure heart or artery disease or any attendant condition.

(j) Any label or labeling containing a statement on cholesterol and fatty acid content not in conformity with this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the Act.

§ 3.41 [Revoked]

2. In Part 3 existing § 3.41 is hereby revoked.

Effective date. All labeling ordered after December 31, 1973, and all labeling used for products shipped in interstate commerce after December 31, 1974, shall comply with this regulation.

(Secs. 201, 403, 701(a), 52 Stat. 1047–1048, as amended, 1055; 21 U.S.C. 321, 343, 371(a))

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[1] Copies of the method may be obtained by writing to Division of Nutrition BF–124, Bureau of Foods, Food and Drug Administration, 200 C Street SW., Washington, DC 20204.

NOTE: Incorporation by reference provisions approved by the Director of the Federal Register, January 15, 1973.

[FR Doc.73–989 Filed 1–18–73;8:45 am]

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

Label Designation of Ingredients for Standardized Foods

A statement of policy, § 3.88 *Label designation of ingredients for standardized foods*, was published in the FEDERAL REGISTER of March 10, 1972 (37 FR 5120). On the basis of questions raised regarding the exemption granted by § 3.88(d), the Commissioner of Food and Drugs has concluded that the exemption should be clarified so that the intent of the regulation, to provide more informative labeling for the consumer, can be achieved with a minimum of confusion and misunderstanding.

In many food standards the name of the principal mandatory ingredient appears in the name of the food, e.g., peaches. Where the standard also provides an option to the variety and form of the unit, e.g., yellow clingstone, yellow freestone—unpeeled whole, peeled slices, a statement designating the optional variety and optional form of the unit used is required to appear in close proximity to the name of the food, e.g., whole yellow cling peaches, sliced yellow freestone peaches. It was not the intention of the Commissioner in promulgating § 3.88(d) to change the requirement that statements that significantly qualify or explain the name of the principal mandatory ingredient should appear prominently and conspicuously in close proximity to the name of the food.

In addition, where certain optional ingredients are used, such as the packing media of canned fruits and canned tuna, smoke flavoring in the case of cheese, or hot dried red peppers in the case of canned corn, statements informing consumers of such use should continue to be placed conspicuously on the principal display panel to facilitate the consumer's choice between the same food containing or not containing such ingredients.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055; 21 U.S.C. 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), § 3.88 is revised to read as follows:

§ 3.88 Label designation of ingredients for standardized foods.

(a) There is significant consumer interest that the labels of standardized foods bear complete information of the ingredients contained in the food. In the absence of legal authority to require that the label bear such information, the Food and Drug Administration encourages all manufacturers, packers, and distributors to voluntarily make such disclosure.

(b) The Food and Drug Administration intends to amend the definitions and standards of identity of food by setting into motion as rapidly as possible the provisions of section 401 of the act to require label declaration of all optional ingredients with the exception of optional spices, flavorings, and colorings which may continue to be designated as such without specific ingredient declaration.

(c) Statutory authority does not exist to require the declaration of mandatory ingredients on the label of standardized foods.

(d) The requirement (set forth in some of the definitions and standards of identity for food) that designated optional ingredients such as spices, flavorings, colorings, emulsifiers, flavor enhancers, stabilizers, preservatives, and sweeteners be declared in a specified manner on the label wherever the name of the standardized food appears on the label so conspicuously as to be easily seen under customary conditions of purchase shall not apply to any manufacturer, packer, or distributor of a standardized food who voluntarily labels such food in the manner indicated by section 403(i) of the act (21 U.S.C. 343(i)), and the regulations promulgated thereunder, and who otherwise complies with such definition and standard. Words and statements that significantly differentiate between several foods complying with the same standard by describing the optional forms or varieties, the packing medium, and significant characterizing ingredients present in the food, shall continue to be declared in the manner as required by the particular standard.

Since this amendment is for the purpose of clarifying an already existing regulation notice and public procedure are not necessary prerequisites to the promulgation of this order.

Effective date. This order shall be effective on January 19, 1973.

(Sec. 701(a); 52 Stat. 1055; 21 U.S.C. 371(a))

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.73–990 Filed 1–18–73;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 1]

IMITATION FOODS

Application of Term "Imitation"

Section 403(c) of the Federal Food, Drug, and Cosmetic Act provides that a food shall be deemed to be misbranded "If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word 'imitation' and, immediately thereafter, the name of the food imitated."

When section 403(c) of the act was adopted in 1938, Congress was seeking to protect the consumer from uninformed purchase of an inferior substitute product, which could be mistaken for a traditional food product.

The courts have long recognized that the term "imitation" suggests an inferior product. In 62 Cases * * * Jam v. United States, 340 U.S. 593, 600 (1951), the U.S. Supreme Court observed that the term "imitation" as applied to jam connotes "a different, an inferior preserve * * *" In United States v. 651 Cases * * * Chocolate Chil-Zert, 114 F. Supp. 430, 432 (N.D.N.Y. 1953), the court stated "[T]he word [imitation] connotes inferiority * * * in the sense that it is cheapened by the substitution of ingredients."

Vast strides in food technology have taken place since section 403(c) of the act was enacted, and there are now on the market many new wholesome and nutritious food products, some of which resemble and are substitutes for other, traditional foods. Significantly, it is no longer the case that such products are necessarily inferior to the traditional foods for which they may be substituted.

There has been some uncertainty as to the proper scope of the term "imitation" in this modern context. The term clearly fails to inform the public of the actual characteristics and properties of a new food product. In its "Report to the President," the White House Conference on Food, Nutrition, and Health held in November and December 1969 recommended that "[o]versimplified and inaccurate terms as 'imitation' should be abandoned as uninformative to the public."

To apply automatically the term "imitation" to new substitute food products which are not nutritionally inferior would be a disservice to consumers and would be contrary to the common understanding that the word "imitation" connotes inferiority. Section 403(c) of the act would then present a serious obstacle to the development and marketing of modified products with improved nutritional content. Indeed, because of the traditional connotation of inferiority, application of the term "imitation" to a substitute food product which is not inferior could be misleading to the consumer, in violation of section 403(a) of the act.

Accordingly, the Commissioner of Food and Drugs has concluded that it is in the interest of consumers and consistent with the general intent of Congress to restrict required application of the term "imitation" to a substitute food which is nutritionally inferior to the food for which it is a substitute.

The consumer, however, must be protected from unwitting purchase of a product which is different, although not inferior, from what he may reasonably expect. The Commissioner concurs with the further recommendation of the White House Conference that the "name of a food should accurately describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients." Accordingly, in order to avoid "imitation" status, a substitute food product which is not nutritionally inferior must also bear a label which clearly states the common or usual name of the product and which is not false or misleading.

The Commissioner has paid particular attention to the definition of "nutritional inferiority". Section 1.17, nutrition labeling, which is published in this issue of the FEDERAL REGISTER provides that a difference of less than 10 percent of the U.S. Recommended Daily Allowance (U.S. RDA) of any vitamin, mineral, or protein is not properly regarded as significant. Accordingly, nutritional inferiority is defined as a reduction in the content of an essential vitamin or mineral or of protein that amounts to 10 percent or more of the U.S. RDA. Any lesser difference is regarded as nutritional equivalence, even though small differences may exist.

The Commissioner has also concluded that, since a reduction in fat content or caloric content may well be desirable, such a reduction should not be regarded as nutritional inferiority as long as the product is labeled pursuant to the provisions of § 1.17, and any labeling with respect to a reduction in caloric content complies with the regulations applicable to caloric content in Part 125. The proper declaration of a reduction in caloric content was included as part of the revision of Part 125 and the resulting 1968–1970 Special Dietary Food Hearings. The Commissioner anticipates that a tentative order on that aspect of the hearings will be issued in the near future. When effective, those regulations will be appropriately referenced in this regulation.

Finally, the Commissioner recognizes that it is impossible to set out in general language in any regulation the precise parameters of nutritional inferiority. Accordingly, it must be recognized that the criteria for nutritional inferiority proposed in this regulation are not all-inclusive, and that the Commissioner reserves the right to make a determination of nutritional inferiority on an ad hoc basis, depending upon the facts of the specific situation. Any such determination falling outside the general proposed criteria in this regulation will be made in writing and sent to the manufacturer or distributor of the food, and an opportunity will be given for changes in the labeling and/or formulation before regulatory action is undertaken.

The Commissioner has considered whether there may be basis for imitation labeling other than nutritional inferiority. In reviewing this matter, it appears that nutritional inferiority is the only type of inferiority that is quantifiable on an objective basis. All other potential aspects of inferiority involve essentially subjective judgment which may vary from person to person. Some individuals may prefer a new food to a traditional food, whereas others may prefer the traditional food. The Commissioner has concluded that it is not the function of the Food and Drug Administration to attempt to arbitrate between the likes and dislikes of different individuals or between the different economic considerations that motivate different producers of agricultural commodities or different manufacturers and distributors of foods. The function of the Food and Drug Administration is solely to assure the safety of all foods and to prevent misleading labeling. This new regulation, which cross-references the proposal previously published in the FEDERAL REGISTER of June 22, 1972 (37 FR 12327) requiring the establishment and use of truthful and accurate descriptive names for all food, will make certain that no food is labeled in a false or misleading way and thus fully implements the mandate given by Congress.

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 403, 701(a), 52 Stat. 1047–48 as amended, 1055; 21 U.S.C. 343, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Part 1 in § 1.8 by adding the following new paragraph:

§ 1.8 Food in package form, labeling; identity.

* * * * *

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and consequently subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to the food imitated.

(2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:

(i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.

(ii) Its label bears a common or usual name that complies with the provisions of § 102.1(a) of this chapter and that is not false or misleading.

(3) The label of a food that is a substitute for and resembles another food shall bear a common or usual name or

an appropriately descriptive term in addition to any fanciful name. Petitions to establish a common or usual name shall be submitted in accordance with the provisions of § 102.1(c) of this chapter.

(4) Nutritional inferiority includes a reduction in the content of an essential vitamin or mineral or of protein that amounts to 10 percent or more of the U.S. Recommended Daily Allowance established under § 1.17(c)(7)(iv), but does not include a reduction in the caloric or fat content provided the food is labeled pursuant to the provisions of § 1.17, and provided that the labeling with respect to any reduction in caloric content complies with the provisions applicable to caloric content in Part 125 of this chapter. If the Commissioner concludes that a food falls within this paragraph in that it is a substitute for and resembles another food but is nutritionally inferior to the food imitated, for reasons other than those set out in this subparagraph, he shall so inform the manufacturer or distributor in writing of his conclusions and shall offer a reasonable time period within which labeling and/or formulation changes may be made prior to the institution of regulatory action.

(5) The provisions of this paragraph do not affect the required declarations of identity under definitions and standards of identity for foods promulgated pursuant to section 401 of the act.

Interested persons may, on or before March 20, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6–88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.73–991 Filed 1–18–73;8:45 am]

[21 CFR Part 1]

FLAVOR, SPICES, AND FOOD CONTAINING ADDED FLAVOR

Proposed Labeling

Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act authorizes the declaration of "spices," "flavorings," and "colorings" when these are used as food ingredients, except in the case of foods sold as spices, flavoring, or colorings.

There is some confusion as to the precise classification of certain substances as spices and flavorings. Artificial flavor is defined by § 1.12(a)(1) (21 CFR 1.12(a)(1)), but definitions for spices and natural flavors have not been established by regulation. Advisory standards were issued in 1918 as Food Inspection Decision (FID) 172, covering the collective term spices, and a number of specific foods were classified as spices. Since that time, this FID and its subsequent revisions have been used within the agency as guides for rendering decisions concerning the classification of selected substances as spices.

Some confusion also exists concerning the classification of certain newer flavors, because certain of their constituent parts are foods per se or are regulated chemicals. Diverse opinions have been offered over the years concerning labeling requirements of new flavors, causing uncertainty in the food industry.

There are at present also no regulations establishing a consistent pattern either for labeling bulk flavors shipped to a food manufacturer for use in making a finished food, or for designating the type of flavor on the label of the finished food.

The Food and Drug Administration is aware that the composition of a proprietary flavor compound marketed by a flavor manufacturer to a food manufacturer is a valuable trade secret. At the same time, the food manufacturer and the public require assurance that the ingredients used in such compounds meet the safety requirements of the law. Accordingly, it is proposed that, in lieu of declaring each separate ingredient on such compounds, a statement will suffice that each ingredient is contained in one of the three Food and Drug Administration flavor regulations, § 121.101, § 121.1163, or § 121.1164 (21 CFR 121.101, 121.1163, or 121.1164); it is also proposed that any ingredient not contained in one of those regulations shall be listed separately on the label.

Recent legal actions demonstrate that incorrect labeling is often used and that a uniform labeling policy for flavor designation should be established. The Food and Drug Administration adopted, in the ice cream standard, § 20.1 (21 CFR 20.1), a labeling pattern for flavor that has been proven to be very clear and informative to consumers. It is therefore proposed that this pattern, with appropriate modification, be extended to all foods.

When a flavor or spice is used as an ingredient in fabricated foods, the flavor or spice is covered by the labeling exemptions in section 403(i)(2) of the act and may be designated as "spices," "flavorings," or "artificial flavorings." There is uncertainty, however, as to the extent the other components of these manufactured flavors or seasonings, e.g., carriers, preservatives, emulsifiers, and enhancers, are exempt from specific ingredient declaration in the finished food.

Historically, the Food and Drug Administration has handled problems related to labeling of ingredients contained in flavors on a case-by-case basis. Specific inquiries from manufacturers and other interested individuals concerning the label declaration of certain nonflavors as ingredients in processed foods have resulted in the issuance of the following advisory opinions:

1. Anticaking agents need not be declared, provided the levels used are so low that they have no functional effect in the food itself.

2. Preservatives need not be declared if they are not intended to, and do not in fact, have any preservative effect on the finished food.

3. Ingredients ordinarily used as vehicles or emulsifiers need not be declared, but unusual solvents or vehicles must be declared.

4. Emulsifiers need not be declared on the label of the finished food if they do not function as such in the finished food.

5. It is necessary to declare the base used, such as sugar, dextrose, or salt.

The inclusion of most nonflavor components of flavor ingredients on the label of the finished food product would be impractical and even misleading to the ultimate consumer, and it is therefore proposed that such label declaration not be required where the nonflavor component(s) has no function in the finished food.

In order to clarify the policy of the Food and Drug Administration on these issues, the Commissioner of Food and Drugs proposes to issue regulations which: (1) Accurately define materials which may be considered flavors and spices; (2) describe specific conditions under which nonflavor ingredients of manufactured flavors are and are not exempt from the requirement of specific label declaration in finished food; (3) list those substances which are considered foods regardless of conditions of use and therefore require a declaration on the label of the finished food; (4) establish specific conditions under which bulk flavors are and are not exempt from the requirement of specific ingredient labeling; (5) establish a uniform pattern for label declaration of flavoring in finished food; and (6) consolidate in one regulation provisions relating to flavor labeling contained in statements of policy (21 CFR 3.10, 3.23(b), and 3.201).

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 403, 701(a), 52 Stat. 1047, 1055; 21 U.S.C. 343, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes to revoke §§ 3.10, 3.23(b), and 3.201 (21 CFR 3.10, 3.23(b), and 3.201), and to amend § 1.12 (21 CFR 1.12) by revising the section title, by revising paragraph (a)(1), by redesignating existing paragraphs (a)(2) and (a)(3) as new paragraphs (a)(4) and (a)(5), by adding new paragraphs (a)(2) and (a)(3), and by adding new paragraphs (g), (h), and (i), as follows:

§ 1.12 Food; labeling; flavoring, spices, or coloring, chemical preservatives.

(a) (1) The term "artificial flavor" or "artificial flavoring" means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf, or similar plant material, meat, fish, or poultry. Artificial flavor includes the substances listed in §§ 121.101(g) and 121.1164(b) of this chapter.

(2) The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form; whose signifi-

cant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in § 121.101(e) of this chapter, such as the following:

Allspice.	Marjoram.
Anise.	Mustard flour.
Basil.	Nutmeg.
Bay leaves.	Oregano.
Caraway seed.	Paprika.
Cardamon.	Parsley leaves.
Celery seed.	Pepper, black.
Chervil.	Pepper, white.
Cinnamon.	Pepper, red.
Cloves.	Rosemary.
Coriander.	Saffron.
Cumin seed.	Sage.
Dill seed.	Savory.
Fennel seed.	Star aniseed.
Fenugreek.	Tarragon.
Ginger.	Thyme.
Horseradish.	Turmeric.
Mace.	

Paprika, turmeric, and saffron are also colors which, under § 1.10(c), shall be declared as "spice and coloring," unless declared by their common or usual name.

(3) The term "natural flavor" or "natural flavoring" means the essential oil, oleoresin, essence or extractive, hydrolysate, distillate, or other reaction product, each of which contains the vital flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, or poultry, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural extractives obtained from plants listed in § 121.101(e) and the substances listed in § 121.1163 of this chapter.

(4) The term "artificial color" or "artificial coloring" means a coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

(5) The term "chemical preservative" means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

* * * * *

(g) A flavor shall be labeled in the following way when shipped to a food manufacturer or processor (but not a consumer) for use in a food that will subsequently be sold at retail.

(1) If the flavor consists of one ingredient, it shall be declared by its common or usual name.

(2) If the flavor consists of two or more ingredients, the label either may declare each ingredient by its common or usual name or may state "All flavor ingredients contained in this product are listed in §§ 121.101, 121.1163, or § 121.1164 of the Food and Drug Administration Regulations" of this chapter in lieu of declaring each such ingredient. Any flavor ingredient not contained in one of these regulations, and any nonflavor ingredient, shall be separately listed on the label.

(3) If the flavor is, or bears or contains, any flavor subject to Part 22 of this chapter, it shall be so labeled.

(4) In cases where the flavor contains solely natural flavor(s), the flavor shall be so labeled. In cases where the flavor contains both a natural characterizing flavor and an artificial flavor simulating it and the natural flavor predominates, the flavor shall be so labeled. In cases where the flavor contains solely artificial flavor(s) or in cases where the flavor contains both a natural characterizing flavor and an artificial flavor simulating it and the artificial flavor predominates, the flavor shall be so labeled.

(h) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way:

(1) Spice, natural flavor, and artificial flavor may be declared as "spice," "natural flavor," or "artificial flavor," or any combination thereof, as the case may be.

(2) A substance which is not spice or flavor, but which is used in the manufacture of spice or flavor for a functional purpose, e.g., a carrier, emulsifier, preservative, enhancer, or potentiator, is an incidental additive and exempt from the requirement of label declaration if each of the following criteria is met:

(i) It is present in the flavor in a quantity not exceeding the amount necessary to produce the intended effect.

(ii) It is present in only trace quantities in the finished food.

(iii) It has no significant nutritive effect in the finished food.

(iv) It has no functional effect in the finished food.

(v) It is not specifically required to be declared by other regulations.

(vi) It is not a food additive as defined in section 201(s) of the act; or if it is a food additive as so defined, it is used in conformity with regulations established pursuant to section 409 of the act.

(3) Substances obtained by cutting, grinding, drying, pulping, or similar processing of tissues derived from fruit, vegetable, meat, fish, or poultry, e.g., powdered or granulated onions, garlic powder, and celery powder, are commonly understood by consumers to be food rather than flavor and shall be declared by their common or usual name.

(4) Any salt (sodium chloride) used as an ingredient in flavor shall be declared by its common or usual name "salt".

(5) Any monosodium glutamate used as an ingredient in flavor shall be declared by its common or usual name "monosodium glutamate".

(6) Any pyroligneous acid (artificial smoke flavor) used as an ingredient in flavor or in a food shall be declared by a phrase such as "pyroligneous acid, an artificial flavor", "pyroligneous acid, an artificial smoke flavor", or "artificially flavored with pyroligneous acid". No representation may be made, either directly or implied, that a food flavored with pyroligneous acid has been smoked or has a true smoked flavor, or that a seasoning sauce or similar product containing pyroligneous acid and used to season or flavor other foods will result in a smoked product or one having a true smoked flavor.

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to flavor, by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, the flavor of the product shall be declared in the following way:

(1) If the food contains no artificial flavor, the name of the food on the principal display panel or panels for the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the name of the food, except that if the food is one that is commonly expected to contain a characterizing ingredient, e.g., strawberries in "strawberry shortcake", and the food contains no such ingredient or contains natural flavor in addition to such ingredient, the name of the characterizing flavor shall be immediately followed by the word "flavored" in letters not less than one-half the height of the letters in the name of the characterizing flavor.

(2) In cases where the food contains both a natural characterizing flavor and an artificial flavor simulating it and the natural flavor predominates, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, in letters not less than one-half of the height of the letters used in the name of the food, followed by the word "flavored", in letters not less than one-half of the height of the letters in the name of the characterizing flavor, e.g., "vanilla flavored", "peach flavored", or "vanilla flavored and strawberry flavored".

(3) In cases where an artificial flavor is used alone, or in cases where the food contains both a natural characterizing flavor and an artificial flavor simulating it and the artificial flavor predominates, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, in letters not less than one-half of the height of the letters used in the name of the food, preceded by the word(s) "artificial" or "artificially flavored", in letters not less than one-half of the height of the letters in the name of the characterizing flavor, e.g., "artificial vanilla", or "artificially flavored strawberry" or "artificially flavored vanilla and artificially flavored strawberry".

(4) If the food is labeled in accordance with paragraph (i)(2) of this section or if it contains any artificial flavor not

simulating the characterizing flavor, the label shall also bear the words "artificial flavor added" or "artificial _____ flavor added" or "and artificial _____ flavor", the blank being filled with the common or usual name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(5) Wherever the name of the characterizing flavor appears on the label (other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, except:

(i) Where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part or is associated with the trademark or brand may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and

(ii) If the finished product contains more than one flavor subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such food, e.g., "vanilla flavored, or chocolate and strawberry flavored, artificial flavors added".

(6) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, e.g., "strawberry and artificial strawberry flavor", or "strawberry, artificial strawberry flavor added".

Interested persons may, on or before March 20, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6–88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Comments received will be available for public inspection at the above office during regular business hours, Monday through Friday.

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.73-992 Filed 1-18-73;8:45 am]

[21 CFR Parts 1, 3, 5]

EXEMPTIONS FROM FOOD LABELING REQUIREMENTS

Notice of Proposed Rule Making

A fabricated food containing two or more ingredients is required by section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act to bear on its label the common or usual name of each ingredient (other than spices, flavorings, and colorings): *Provided*, That, to the extent that such listing of ingredients is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

The Food and Drug Administration has promulgated a limited number of regulations exempting specific incidental food additives from the requirements of section 403(i)(2) of the act. The Commissioner proposes to clarify the Agency's policy with regard to the label declaration of incidental additives and to consolidate in one place the regulations concerning label exemptions currently found in 21 CFR Parts 1, 3, and 5.

The Commissioner proposes to revoke § 5.5, which was stayed at 31 FR 15730 on December 14, 1966, on the ground that 21 CFR 121.4001 (37 FR 2437) established the type of restrictions contained in § 5.5 for saccharin, the only artificial sweetener known to the Commissioner to be in use at the present time. Any other artificial sweetener will also be subject to a regulation promulgated under section 409 of the act, and will similarly include the type of restrictions contemplated by § 5.5. Accordingly, the provisions of § 5.5 are entirely obsolete. The Commissioner also proposes to revoke §§ 5.9 and 5.10, and to transfer the remainder of Part 5 and § 3.26 to a new § 1.10a. It is proposed to include in new § 1.10a provisions defining incidental additives and exempting them from the labeling requirements of section 403(i)(2) of the act, which cover the substance of former §§ 5.9 and 5.10, and to transfer exemptions from the labeling requirements of section 403(i)(2) of the act found in § 1.10 to the new § 1.10a. In addition, it is proposed that the termination of old exemptions, published as § 3.1 in 1961, be revoked as obsolete since manufacturers are now fully aware that these foods are no longer exempt from section 403(i)(2) of the act.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 403, 701(a), 52 Stat. 1048, 1055; 21 U.S.C. 343, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Parts 1, 3, and 5 be amended as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

§ 1.10 [Amended]

1. In § 1.10 paragraphs (e), (f), and (g) are hereby revoked, and paragraph (h) is redesignated as paragraph (e).

2. A new § 1.10a is added to Part 1, incorporating the substance of § 1.10 (e), (f), and (g), § 3.26, §§ 5.1 through 5.4 and §§ 5.6 through 5.8 with additional new provisions, and reading as follows:

§ 1.10a Food; labeling; exemptions from labeling requirements.

(a) The following foods are exempt from compliance with the requirements of section 403(i)(2) of the act (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients).

(1) An assortment of different items of food, when variations in the items that make up different packages packed from such assortment normally occur in good packing practice and when such variations result in variations in the ingredients in different packages, with respect to any ingredient that is not common to all packages. Such exemption, however, shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement (in terms that are as informative as practicable and that are not misleading) indicating that other ingredients may be present.

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either (i) the labeling of the bulk container plainly in view or (ii) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(i)(2) of the act.

(3) Propylene glycol or glycerin present in quiescently frozen confections because of use as a carrier for food-grade emulsifiers and stabilizers.

(4) Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of this subparagraph, incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(*a*) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(*b*) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

(*c*) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

(iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(b) A food repackaged in a retail establishment is exempt from the following provisions of the act if the conditions specified are met.

(1) Section 403(e)(1) of the act (requiring a statement on the label of the

name and place of business of the manufacturer, packer, or distributor).

(2) Section 403(g)(2) of the act (requiring the label of a food which purports to be or is represented as one for which a definition and standard of identity has been prescribed to bear the name of the food specified in the definition and standard and, insofar as may be required by the regulation establishing the standard the common names of the optional ingredients present in the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required by these provisions.

(3) Section 403(i)(1) of the act (requiring the label to bear the common or usual name of the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the common or usual name of the food, or if the common or usual name of the food is clearly revealed by its appearance.

(c) An open container (a container of rigid or semirigid construction, which is not closed by lid, wrapper, or otherwise) of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than 1 dry quart, shall be exempt from the labeling requirements of sections 403 (e), (g)(2) (with respect to the name of the food specified in the definition and standard), and (i)(1) of the act; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of such containers enclosed therein and the quantity of the contents of each.

(d) Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (j), and (k) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will insure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such food from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(3) The article is an egg product subject to a standard of identity promulgated in Part 42 of this chapter, is to be shipped under the conditions specified in paragraph (a) or (b) of this section and for the purpose of pasteurization or other treatment as required in such standard, and each container of such egg product bears a conspicuous tag or label reading "Caution—This egg product has not been pasteurized or otherwise treated to destroy viable Salmonella micro-organisms." In addition to safe and suitable bactericidal processes designed specifically for Salmonella destruction in egg products, the term "other treatment" in the first sentence of this paragraph shall include use in acidic dressings in the processing of which the pH is not above 4.1 and the acidity of the aqueous phase, expressed as acetic acid, is not less than 1.4 percent, subject also to the conditions that:

(i) The agreement required in paragraph (b) of this section shall also state that the operator agrees to utilize such unpasteurized egg products in the processing of acidic dressings according to the specifications for pH and acidity set forth in this paragraph, agrees not to deliver the acidic dressing to a user until at least 72 hours after such egg product is incorporated in such acidic dressing, and agrees to maintain for inspection adequate records covering such processing for 2 years after such processing.

(ii) In addition to the caution statement referred to above, the container of such egg product shall also bear the statement "Unpasteurized ——— for use in acidic dressings only," the blank being filled in with the applicable name of the eggs or egg product.

(e) Conditions affecting expiration of exemptions. (1) An exemption of a shipment or other delivery of a food under paragraph (d) (1) or (3) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(2) An exemption of a shipment or other delivery of a food under paragraph (d) (2) or (3) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by paragraph (d) (2) or (3) of this section.

(3) An exemption of a shipment or other delivery of a food under paragraph (d)(2) or (3) of this section shall expire:

(i) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(ii) Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such paragraph.

(f) The word "processed" as used in this paragraph shall include the holding of cheese in a suitable warehouse at a temperature of not less than 35° F. for the purpose of aging or curing to bring the cheese into compliance with requirements of an applicable definition and standard of identity. The exemptions provided for in paragraph (d) of this section shall apply to cheese which is, in accordance with the practice of the trade, shipped to a warehouse for aging or curing, on condition that the cheese is identified in the manner set forth in one of the applicable following paragraphs, and in such case the provisions of paragraph (e) of this section shall also apply:

(1) In the case of varieties of cheese for which definitions and standards of identity require a period of aging whether or not they are made from pasteurized milk, each such cheese shall bear on the cheese a legible mark showing the date at which the preliminary manufacturing process as been completed and at which date curing commences, and to each cheese, on its wrapper or immediate container, shall be affixed a removable tag bearing the statement "Uncured ——— cheese for completion of curing and proper labeling," the blank being filled in with the applicable name of the variety of cheese. In the case of swiss cheese, the date at which the preliminary manufacturing process had been completed and at which date curing commences is the date on which the shaped curd is removed from immersion in saturated salt solution as provided in the definition and standard of identity for swiss cheese, and such cheese shall bear a removable tag reading, "To be cured and labeled as 'swiss cheese,' but if eyes do not form to be labeled as 'swiss cheese for manufacturing.'"

(2) In the case of varieties of cheeses which when made from unpasteurized milk are required to be aged for not less than 60 days, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading, "——— cheese made from unpasteurized milk. For completion of curing and proper labeling," the blank being filled in with the applicable name of the variety of cheese.

(3) In the case of cheddar cheese, washed curd cheese, colby cheese, granular cheese, and brick cheese made from unpasteurized milk, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been

completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading "——— cheese made from unpasteurized milk. For completion of curing and proper labeling, or for labeling as ——— cheese for manufacturing," the blank being filled in with the applicable name of the variety of cheese.

(g) The label declaration of a harmless marker used to identify a particular manufacturer's product may result in unfair competition through revealing a trade secret. Exemption from the label declaration of such a marker is granted, therefore, provided that the following conditions are met:

(1) The person desiring to use the marker without label declaration of its presence has submitted to the Commissioner of Food and Drugs full information concerning the proposed usage and the reasons why he believes label declaration of the marker should be subject to this exemption; and

(2) The person requesting the exemption has received from the Commissioner of Food and Drugs a finding that the marker is harmless and that the exemption has been granted.

(h) Wrapped fish fillets of nonuniform weight intended to be unpacked and marked with the correct weight at the point of retail sale in an establishment other than that were originally packed shall be exempt from the requirement of section 403(e)(2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing and marking:

(1) *Provided*, That:

(i) The outside container bears a label declaration of the total net weight; and

(ii) The individual packages bear a conspicuous statement "To be weighed at time of sale" and a correct statement setting forth the weight of the wrapper: *And*

(2) *Provided further*, That it is the practice of the retail establishment to weigh and mark the individual packages with a correct net-weight statement prior to or at the point of retail sale. A statement of the weight of the wrapper shall be set forth so as to be readily read and understood, using such term as "wrapper tare — ounce," the blank being filled in with the correct average weight of the wrapper used.

(3) The act of delivering the wrapped fish fillets during the retail sale without the correct net-weight statement shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for wrapped fish fillets delivered into institutional trade provided the outside container bears the required information.

(i) Wrapped clusters (consumer units) of bananas of nonuniform weight intended to be unpacked from a master carton or container and weighed at the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirements of section 403(e)(2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing:

(1) *Provided*, That:

(i) The master carton or container bears a label declaration of the total net weight; and

(ii) The individual packages bear a conspicuous statement "To be weighed at the time of sale" and a correct statement setting forth the weight of the wrapper:

(2) *And provided, further*, That it is the practice of the retail establishment to weigh the individual packages either prior to or at the time of retail sale.

(3) The act of delivering the wrapped clusters (consumer units) during the retail sale without an accurate net weight statement or alternatively without weighing at the time of sale shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for clusters (consumer units) delivered into institutional trade, provided that the master container or carton bears the required information.

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

§ 3.1 [Revoked]

3. The provisions of § 3.1 are hereby revoked.

§ 3.26 [Revoked]

4. The provisions of § 3.26 are hereby revoked.

PART 5—[REVOKED]

5. The provisions of Part 5 are hereby revoked.

Interested persons may, on or before March 20, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6–88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.73–993 Filed 1–18–73;8:45 am]

[21 CFR Parts 1, 3, 125]

SPECIAL DIETARY FOODS

Label Statements; Proposed Findings of Fact, Conclusions, and Tentative Order Following Public Hearing

In the matter of revising regulations for food for special dietary uses:

HISTORY

1. On the initiative of the Commissioner of Food and Drugs, a notice of proposed rule making in the above-identified matter was published in the FEDERAL REGISTER of June 20, 1962 (27 FR 5815), and numerous comments were received in response thereto. Subsequently, orders were published in the FEDERAL REGISTER of June 18, 1966 (31 FR 8521 et seq.), to become effective December 15, 1966, deleting § 1.11 (21 CFR 1.11), excepting from labeling requirements certain artificially sweetened foods (21 CFR 5.5), establishing definitions and standards of identity for dietary supplements of vitamins and minerals and for vitamin and mineral-fortified foods (21 CFR Part 80), and revising the regulations for the labeling of food for special dietary uses (21 CFR Part 125).

2. During the 30-day period provided by the orders of June 18, 1966, objections and requests for a public hearing were filed. Consequently, an order was published in the FEDERAL REGISTER of December 14, 1966 (31 FR 15730), staying the effective date of § 5.5, Part 80, and Part 125, and staying the effective date of the deletion of § 1.11, as published June 18, 1966. The order of December 14, 1966, gave notice that a public hearing would be held on the basis of the objections received, and set forth the issues to be decided at the hearing. Since the order also contained amendments to the provisions of Parts 80 and 125 published in the FEDERAL REGISTER of June 18, 1966, an additional period of 30 days was provided for the filing of objections by persons adversely affected. Numerous letters objecting to the amendments and requesting a public hearing were received; however, no substantive issues not already stated in the order of December 14, 1966, were raised by these objections. A correction of a printer's error in the order of December 14, 1966, was published in the FEDERAL REGISTER of December 21, 1966 (31 FR 16312).

3. Also published in the FEDERAL REGISTER of December 14, 1966 (31 FR 15746), was a notice proposing that § 80.2, the definition and standard of identity for vitamin- and mineral-fortified foods, which was established by the order of June 18, 1966, and amended and stayed by the order of December 14, 1966, be amended by adding to the table in paragraph (c) the following classes of food: (1) Frozen dessert products (containing vegetable fat in lieu of butter fat) made in semblance of ice cream or ice milk; (2) milk fortifiers; (3) and meal substitutes.

4. The comments received in response to the proposal of December 14, 1966, were considered and an order was subsequently published in the FEDERAL REGISTER of April 8, 1967 (32 FR 5736), amending § 80.2 to add the additional classes of food. In response to that order, several objections and requests for a public hearing were received; however, no substantive issues were raised that were not already set forth in the order of December 14, 1966.

5. A notice was published in the FEDERAL REGISTER of April 2, 1968 (33 FR 5268), scheduling a hearing to begin May 21, 1968, and a prehearing confer-

ence to begin May 7, 1968. The notice also designated Mr. David H. Harris as the Hearing Examiner for these proceedings, and notice that he was appointed a hearing examiner was published in the FEDERAL REGISTER of May 4, 1968 (33 FR 6828).

6. The hearing was convened as scheduled May 21, 1968, and recessed the same day to permit continuation of prehearing conferences. Notice was given in the FEDERAL REGISTER of June 13, 1968 (33 FR 8679), that the hearing was being reconvened June 20, 1968. The hearing was reconvened as scheduled and continued for almost 2 years, closing on May 14, 1970.

7. The taking of evidence with reference to infant foods was closed October 14, 1969. Pursuant to 21 CFR 2.96, and limited to the infant food portion of the proceedings, the Hearing Examiner submitted his report and certified the record together with his report to the Commissioner of Food and Drugs. This Hearing Examiner's report, dated August 26, 1970, is part of the public record (Docket No. FDC–79) on file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6–88, 5600 Fishers Lane, Rockville, MD 20852.

8. The Hearing Examiner subsequently submitted his report of the entire proceedings, except for the previously submitted portion on infant foods, and certified the associated record together with his report to the Commissioner of Food and Drugs. This Hearing Examiner's report, dated January 25, 1971, is part of the public record (Docket No. FDC–78) and is also on file with the Hearing Clerk.

9. After review of the Hearing Examiner's report and related material on the infant foods portion of the proceedings, the Commissioner published in the FEDERAL REGISTER October 29, 1970 (35 FR 16737), proposed findings of fact, proposed conclusions, and a tentative order on label statements relating to infant foods, and provided a 30-day period for the filing of written exceptions. After review of comments received, and further review of the Hearing Examiner's report and related material, several changes were made in the tentative order, and the final order on label statements relating to infant foods (21 CFR 125.5) was published in the FEDERAL REGISTER of December 10, 1971 (36 FR 23553), with an effective date 90 days from the date of publication.

10. After review of the Hearing Examiner's report and related material on the portion of the proceedings concerning vitamin- and mineral-fortified foods, the Commissioner concluded that it would be in the public interest to develop regulations for such foods utilizing the approach of establishing nutritional quality guidelines for certain classes of foods, including those to which vitamins and/or minerals may be added. These guidelines may replace the approach of developing standards of identity for these foods as originally proposed in the form of 21 CFR 80.2. A notice of proposed rule making on nutritional quality guidelines was published in the FEDERAL REGISTER of December 23, 1971 (36 FR 24822). In that notice, the Commissioner proposed to amend Chapter I by adding a new Part 100 for nutritional quality guidelines for foods, defined general principles (proposed 21 CFR 100.1), and proposed the first nutritional quality guideline, in this case for precooked frozen convenience "heat and serve" dinners (proposed 21 CFR 100.20). The Commissioner is deferring final action on 21 CFR 80.2 until experience is gained under 21 CFR Part 100. In a notice of proposed rule making, published elsewhere in this issue of the FEDERAL REGISTER, the Commissioner proposes to establish a new 21 CFR 1.10a (Exemptions From Food Labeling Requirements) which would revoke 21 CFR 5.5, which was stayed at 31 FR 15730 on December 14, 1966, on the ground that 21 CFR 121.4001 (37 FR 2437) established the type of restrictions contained in 21 CFR 5.5 for saccharin (the only artificial sweetener known to the Commissioner to be used at the present time). Any other artificial sweetener will also be subject to a regulation promulgated under section 409 of the Federal Food, Drug, and Cosmetic Act and will similarly include the type or restrictions contemplated by 21 CFR 5.5.

11. In the past, the term "special dietary food" has been defined to include any food to which a nutrient has been added or for which nutrition claims or information have been used. This assured that such foods would have labeling information about the nutrient(s) added, pursuant to regulations promulgated in 21 CFR Part 125. The Commissioner has reviewed the history of this use of the "special dietary" designation, and has concluded that because of the complexity of the conventional food supply that it is necessary to develop general nutrition labeling available for use on all foods. Nutrition labeling is the required form of labeling for foods with added nutrients or for which the manufacturer makes nutrition claims. A notice of proposed rule making on nutrition labeling under title 21 was published in the FEDERAL REGISTER of March 30, 1972 (37 FR 6493).

12. In this issue of the FEDERAL REGISTER, the Commissioner has published the following proposals, tentative orders, and regulations that relate to other sections of special dietary labeling and nutrition labeling as follows:

(a) Nutrition labeling. (§ 1.17)

(b) Food label information panel. (§ 1.8d)

(c) Food fat labeling. (§ 1.18)

(d) Standard of identity for vitamin-mineral supplements. (§ 80.1)

(e) Food standard labeling changes.

(f) Uniform effective date for food labeling changes.

13. Beginning with the enactment of the Federal Food, Drug, and Cosmetic Act of 1938 (52 Stat. 1040), the Food and Drug Administration rendered informal opinions on many problems that arose under the act. These opinions, issued as Trade Correspondence (TC), represented the policy of the Food and Drug Administration based on specific problems and the application of the statute thereto. To avoid confusion as to the status of those TC issuances which will be superseded by the amendments to 21 CFR Part 125 as contained herein and new § 80.1 published elsewhere in this issue of the FEDERAL REGISTER, the Commissioner concludes that such TC issuances should be formally rescinded. Therefore, notice is given that the following TC issuances are rescinded effective on the effective date of the amendments to 21 CFR Part 125 set forth below:

(a) TC–93: Vitamins.

(b) TC–315: Vitamin-carrying oil—labeling.

(c) TC–363: "Vitamin B complex".

(d) TC–379: Wheat germ oil—vitamin E.

(e) TC–387: Vitamin capsules and tablets.

(f) TC–407: Vitamin B_1 tablets for use in enriching bread.

(g) TC–408: Pyridoxine and pantothenic acid in yeast tablets.

(h) TC–411: Bakery products containing thiamine, riboflavin, niacin, and iron.

LIMITED SCOPE OF THIS ACTION

14. This document pertains only to regulations concerning certain limited matters relating to labeling foods for special dietary use (21 CFR 125.1–125.3).

15. A final order was published in the FEDERAL REGISTER of December 10, 1971, on label statements relating to infant foods (§ 125.5). The order of December 10, 1971, and the present action reflect the continuing intent of the Commissioner of Food and Drugs to promulgate revised individual sections of this Part 125 as soon as the records of the hearing can be reviewed, analyzed, and the findings implemented.

16. The document of December 14, 1966, listed the issues for the contemplated hearing, including Nos. III–A, III–B, and III–C, as follows:

III. Issues concerning Part 125. A. With respect to § 125.1 *Definitions and interpretations of terms:*

1. Whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods for special dietary uses, to define "special dietary use" as set forth in § 125.1(a).

2. Whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods for special dietary uses, to establish "recommended dietary allowances" for essential nutrients.

3. Whether the "recommended dietary allowances" as set forth in §125.1(b), and amended by this order, are reasonable.

4. Whether the definition of "artificial sweetener" in § 125.1(c) is reasonable.

B. With respect to § 125.2 *General label statements; dietary properties; value; placement,* whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods for special dietary uses, to require that the labels of such foods bear a statement as required and limited by that section, as amended by this order.

C. With respect to § 125.3 *Label statements relating to vitamins and minerals,* whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods for special dietary uses, to require that the labels of such foods by reason of their vitamin or mineral content bear a statement of the per-

centages of the recommended dietary allowances of such vitamins and minerals contained in such food, with the limitation that vitamin and mineral supplements and foods fortified with vitamins and/or minerals may not bear on their labels a declaration of any quantity of added vitamins or minerals in the supplements or fortified foods which supply more than 100 percent of the recommended dietary allowance for any nutrient.

17. The public hearing in the overall matter was closed May 14, 1970, Pursuant to 21 CFR 2.96, the Hearing Examiner, Mr. David H. Harris, submitted his report in this matter and certified the record together with this report to the Commissioner of Food and Drugs. The report is part of the public record (Docket No. FDC–78) on file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6–88, 5600 Fishers Lane, Rockville, MD 20852.

18. The Commissioner realizes that legal challenge may be brought against the new approach to nutrition labeling in 21 CFR 1.17. If 21 CFR 1.17 is found invalid for any reason it will be necessary to resume the labeling of foods with added nutrients, or for which nutritional claims are made, under 21 CFR Part 125. The Commissioner is therefore keeping the record on this portion of the hearing open, for this limited purpose, in the event that it becomes necessary to amend this tentative order or to issue a supplemental tentative order to provide for labeling of this type pursuant to 21 CFR Part 125 in lieu of 21 CFR 1.17.

Other Regulations and Policies Affected

The publication of this tentative order requires changes in certain existing food additive regulations and formal statements of policy under Parts 1 and 3 of Title 21 of the Code of Federal Regulations. These additional actions are as follows:

1. Since it is no longer appropriate § 1.11 *Special dietary uses* is being revoked.

2. Since the Food and Nutrition Board, National Academy of Sciences-National Research Council (NAS/NRC), has now established a set of Recommended Daily Dietary Allowances for vitamin E, and since there now is scientific evidence that the vitamin E content of the diet may not always be adequate to meet requirements, the formal statement of policy under § 3.9 *Label declaration of vitamin E in food for special delivery use* is being revoked.

3. Since appropriate and useful levels of vitamin B_{12} and folic acid have been determined, the formal statement of policy under § 3.32 *Label declarations of vitamin B_{12} and folic acid in foods for special dietary uses* is being revoked.

4. Since it is no longer appropriate, the formal statement of policy under § 3.46 *Interpretations of orders relating to dietary supplements; vitamin and mineral-fortified foods; foods for special dietary use* is being revoked.

5. Concerning folic acid (folacin), the Food and Nutrition Board, NAS/NRC, recommends daily intakes of 0.4 milligram for older children and adults, and 0.8 milligram during pregnancy. The Council on Foods and Nutrition, American Medical Association (AMA), recently reviewed the subject of desirable levels of folic acid in dietary supplements, and communicated their conclusions to the Food and Drug Administration by their letter of October 13, 1971. The Council recommended increasing the allowable maximum amount to that recommended by the Food and Nutrition Board on the basis of recent evidence of inadequate intakes in significant segments of the population, the absence of ill-effects in normal individuals from such intakes, and the lack of evidence that such intakes aggravate or mask pernicious anemia or interfere with the diagnosis or treatment of the disease. The Commissioner considers these positions of the NAS/NRC and the AMA to be nutritionally sound. Therefore, the formal statement of policy under § 3.42 *Status of pteroylglutamic acid (folic acid) in foods for special dietary use and as a drug* will be revised at a later date to reflect these quantitative changes relative to folic acid. Also, the limitation of 0.1 milligram provided for in the food additive regulation under § 121.1134 *Pteroylglutamic acid* will be revised to permit larger amounts of folic acid in dietary supplements consistent with the recommendations of the Food and Nutrition Board.

6. Since it has now been established that 0.3 milligram of iodine per day is safe in humans, including during pregnancy and lactation, since iodine deficiency goiter continues to persist in the United States, and since 0.3 milligram is a reasonable maximum daily intake to be provided by a dietary supplement for pregnancy and lactation, § 121.1073 *Potassium iodide* and § 121.1149 *Kelp* will be revised at a later date to increase the maximum daily intake of the additives to a level not to exceed 0.3 milligram of iodine.

Having considered the evidence pertaining to the issues concerning §§ 125.1, 125.2, and 125.3 received at the hearing and the Hearing Examiner's Report of January 25, 1971, and having considered the comments from the National Food Advisory Committee, the Commissioner, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 403(j), 701(e), 52 Stat. 1046, 1048, 1055–1056, as amended by 70 Stat. 919; 21 U.S.C. 341, 343(j), 371(e)) and under authority delegated to him (21 CFR 2.120), proposes the following findings of fact, conclusions of law, and tentative final order:

Proposed Findings of Fact[1]

1. Since enactment, in 1941, of the currently effective regulations concerning foods for special dietary uses, the definition of special dietary use contained therein (21 CFR 1.11[1]) has proved inadequate, in certain respects, to meet the needs of the Food and Drug Administration in its regulatory activity. (Swain, Tr. 115, 116, 125–127, 153–155, 168, 169)

2. The term "special dietary use," as applied to food including dietary supplements used by man, means a particular use for which a product purports or is represented to be used, including but not limited to the following uses:

(a) Supplying a special dietary need that exists by reason of a physical, physiological, or other condition, including but not limited to the conditions of convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, diabetes mellitus, or the need to control the intake of sodium;

(b) Supplying a vitamin, mineral, or other dietary property for use by man to supplement his diet by increasing the total dietary intake.

(c) Supplying a special dietary need by reason of being a food for use as the sole item of the diet. (Mickelsen, Tr. 2508; WD–G–Ross, Q&A 55, 56; WD–G–Moses, Q&A 17–19)

3. To fully inform the purchaser of the product's value for such use, the label of a food for a special dietary use should bear a statement of usefulness consisting of a list of the dietary properties upon which the special use is based. (Grollman, Tr. 1766; Hodges, Tr. 2969–70; Mickelsen, Tr. 2518–19; WD–G–Moses, Q&A 33) Many dietary supplements include named ingredients which are of no value as supplements to the human diet. (Grollman, Tr. 1626, 1675–77, 1707, Exhibit P–125, Mickelsen, Tr. 2464–65, Exhibit P–172, 2469, Exhibit P–173, Hodges, Tr. 2933, Exhibit P–179, 2936, Exhibit P–180, Herbert, Tr. 9891, Exhibit P–113, 9899, Exhibit P–468, Swain, Tr. 185–191, 213, 220, 221, 223, 229–231, 255, 264, 269, 336, 397, 442, 447, 455, 469, 475, 476, 487, Weissenberg, Tr. 8761, 6402, 5949, Exhibit P–576, P–591) However, many consumers will purchase such products with long lists of ingredients, believing them to be of better value than products with a lesser number of ingredients. (WD–G–Perloff, Q&A 38–41; Exhibit P–1151, page B9). Such consumers believe that if an ingredient is listed, it must significantly contribute to the value of the product as a dietary supplement. (WD–G–Perloff, Q&A 18, 19; Exhibit P–737) The label of a dietary supplement, as a food for special dietary use, should bear a statement of usefulness consisting of a list of the nutrient ingredients which provide the special use characteristics. The list of such ingredients should be limited to those which are of significant value and need in human nutrition as components of dietary supplements. (Grollman, Tr. 1766; Hodges, Tr. 2969–2970; Mickelsen, Tr. 2518–2520; WD–G–Moses, Q&A 33; WD–C–Ross, Q&A 59–61)

4. It is scientifically inaccurate to list a dietary property of a food for special dietary use that is of no significance in

[1] The abbreviations in the citations are:
Tr.—For transcript pages of the hearing.
P.—For exhibits introduced by the Government, the proponent.
O.—For exhibits introduced by opponents.
WD–G—For written direct testimony by a witness for the Government.
WD–3A—For written direct testimony by a witness for the designated opponent (e.g., "3A").
Q. & A.—Question and answer.

human nutrition, and listing of dietary properties should be limited to ingredients of significant value and need in human nutrition. (WD–G–Ross, Q&A 59–61; Grollman, Tr. 1766; Mickelsen, Tr. 2518–19; Hodges, Tr. 2969–70)

5. In addition to statements on the container label of a food for special dietary use it is necessary to consider the label in its entire setting including statements made in the labeling, promotional material, and advertising for such food, to determine whether the label bears a statement concerning properties of the food which are of no significance in human nutition. (WD–G–Perloff, Q&A 10, 16, 17; WD–G–Swanson, Q&A 50; WD–G–Ross, Q&A 61; Section 201(n), FDCA)

6. The term "minimum daily requirement" was adopted by the Food and Drug Administration in 1940 as a means of fully informing consumers about vitamins and minerals in food for special dietary uses. (Boehne, Tr. 2702–03; Swain, Tr. 170) The term "minimum daily requirements," as it has been used since 1940, in the labeling and promotional material for foods with special dietary uses has led to some confusion among consumers. Consumers believe that the "minimum" requirements may be, or may nearly be, inadequate in terms of the nutrient content provided. (Boehne, Tr. 2704; Weissenberg, Tr. 5891, 7734, 8783; WD–G–Gullberg, Q&A 20; WD–G–Perloff, Q&A 35, 37; Exhibit P–737) The continued existence of the term "minimum daily requirement" has led to the production, promotion, and sale of a variety of dietary supplements, that contain large multiples of the minimum daily requirements for vitamins and minerals, and by far exceed the adequate human total daily dietary requirements for these nutrients. (Boehne, Tr. 2739; Grollman, Tr. 1682 (Exhibit P–84), 1685 (Exhibit P–85); Hodges, Tr. 2933–37 (Exhibit P–181), 2939–40; Herbert, Tr. 9898 (Exhibit P–232), 9899–9901 (Exhibit P–468); Mickelsen, Tr. 2448 (Exhibit P–167); Hodges, Tr. 2942 (Exhibit P–183); Swain, Tr. 171–175, 180–182; Weissenberg, Tr. 8760 (Exhibit P–575, P–583))

7. It will prove beneficial to consumers and simplify the task of consumer education to provide for use of the term "recommended daily allowance" (RDA) as a substitute for "minimum daily requirement" (MDR). (Sebrell, Tr. 26181; WD–G–Gullberg, Q&A 21)

8. The "Recommended Dietary Allowances," revised periodically by the Food and Nutrition Board of the National Research Council, National Academy of Sciences, represent established nutrient levels that are quantitatively high enough to provide for the adequate intake of essential nutrients under the wide variety of conditions that exist in this country for essentially all of the normal healthy persons in the United States. Furthermore, these levels are reviewed, discussed, and accepted by numerous scientists and, therefore, are considered to be extremely reliable. (Hodges, Tr. 2880, 2919, 2964–65; Grollman, Tr. 1670, 1763; Mickelsen, Tr. 2438–39; Herbert Tr. 9865–67; WD–G–Harrison, Q&A 23; Schweigert, Tr. 8257, 8260; WD–G–Gullberg, Q&A 19; Exhibit P–651; Sebrell, Tr. 26, 181)

9. Publication No. 1694 of the National Academy of Sciences entitled "Recommended Dietary Allowances, Seventh Revised Edition, 1968, A Report of the Food and Nutrition Board, National Research Council," and subsequent editions, should be used as the source of authentic and reliable information on which to base recommended daily allowances of nutrients. (WD–3A–Sebrell, Q&A 9, 10, 18, 19, Tr. 26181; Hodges, Tr. 2917; Herbert, Tr. 9865; WD–G–Harrison, Q&A 14, 23, 26, 27; WD–G–Ross, Q&A 65)

10. Recommended dietary allowances adapted from publication No. 1694 of the National Academy of Sciences are sufficiently above the average requirement for particular nutrients to cover the needs of between 95 percent and 99 percent of the normal healthy population. (Hodges, Tr. 7083; WD–46–Olsen, page 7, Tr. 29466–67; Jukes, Tr. 28688; Briggs, Tr. 28761; Mayer, Tr. 28865–66; Stokstad, Tr. 26742; Goodhart, Tr. 30169–70; Stare, Tr. 29280; WD–G–Ross P–5)

11. The essential vitamins are: Vitamins A, C (ascorbic acid), D, E, K, B_1 (thiamine), B_2 (riboflavin), niacin vitamin B_6, folic acid (folacin), pantothenic acid, vitamin B_{12}, and biotin. (WD–3A–Sebrell, Q&A 4, WD–G–Harrison, Q&A 20)

12. The essential mineral nutrients are: Calcium, chlorine, iron, magnesium, phosphorus, potassium, sodium, sulfur, copper, fluorine, iodine, manganese, and zinc. (WD–3A–Sebrell, Q&A 4)

13. The values for vitamins and minerals in the table entitled "Recommended Daily Dietary Allowances," in publication No. 1694 of the National Academy of Sciences, and values for essential nutrients derived from sections in the text when no values are given in the aforementioned table, may be used as a basis for fully informing the purchaser of the nutrient value of a food for special dietary use. A reasonable and scientifically accurate adaptation of the table and text referred to above reads as follows:

Vitamins and minerals	Unit of measurement	Infants and children under 4 years of age	Adults and children 4 or more years of age	Pregnant or lactating women
Vitamin A	International units	2,500	5,000	8,000
Vitamin D	do	400	400	400
Vitamin E	do	10	30	30
Vitamin C	Milligrams	40	60	60
Folic acid	do	0.2	0.4	0.8
Thiamine	do	0.7	1.5	1.7
Riboflavin	do	0.8	1.7	2.0
Niacin	do	9.0	20	20
Vitamin B_6	do	0.7	2.0	2.5
Vitamin B_{12}	Micrograms	3	6	8
Biotin	Milligrams	0.15	0.3	0.3
Pantothenic Acid	do	5.0	10	10
Calcium	Grams	0.8	1.0	1.3
Phosphorus	do	0.8	1.0	1.3
Iodine	Micrograms	70	150	150
Iron	Milligrams	10	18	18
Magnesium	do	200	400	450
Copper	do	1.0	2.0	2.0
Zinc	do	5.0	15	15

14. There are scientific and medical justifications for selecting an age separation at under 4 years of age for the purpose of establishing a basis for dietary supplements. (WD–33–Krehl, pages 5–8; WD–33–Emerson, pages 4–5; WD–43–Filer, page 21) The recommended daily dietary allowance of the Food and Nutrition Board, NAS–NRC, for 2- to 3-year olds can safely be used by infants and 1- to 2-year olds, and the maximum values for the under-4-years-old group can be used for all infants and children under 4 years of age. (WD–33–Krehl, pages 6–7; Tr. 2, 877–8, Hodges; WD–43–Graham; and WD–43–Filer, page 21)

15. There are demonstrable distinctions among the nutritional requirements of infants and young children, and pregnant or lactating women, as compared to the nutritional requirements of adults. (Michelsen, Tr. 2424–2427; Grollman, Tr. 1665; Hodges, Tr. 2877–2878; Herbert, Tr. 9944; WD–3A–Sebrell, Q&A 15, 16, 19, and 28; WD–G–Ross, Q&A 23, Boehne, Tr. 2741–2759)

16. The label of a food purported or represented to be for special dietary use by reason of its vitamin or mineral properties, should bear a statement revealing the proportion or percentage of the recommended daily allowance of the particular vitamins or minerals contained in a specified quantity of the product when consumed during a period of 1 day. This is both reasonable and necessary for an intelligent scientific evaluation of the article. (Herbert, Tr. 9944–5; Grollman, Tr. 1762; Hodges, Tr. 2964–6; WD–G–Ross, Q&A 63; Michelsen, Tr. 2635–7)

17. When a food is purported or represented to be for special dietary use because of certain vitamin or mineral properties, and is offered for use by more than one of the groups for which the recommended daily allowances for the vitamins and minerals are set, it then becomes necessary to state the percent or proportion of the recommended daily allowances for each group separately. (Herbert, Tr. 9945–6; WD–G–Gullberg, Q&A 17; Hodges, Tr. 2966–7)

18. It makes no difference from a scientific point of view when the proportion of the recommended daily allowance amounts to a whole number and a fraction, if the fraction is discarded. (Herbert, Tr. 9946)

19. The term "artificial sweetener" means a sweetening substance not used

in normal metabolism as a source of calories. (WD–G–Levine, Q&A 75–77, 81; WD–G–Ricketts, Q&A 34–35, 39)

20. Occasionally, in the manufacturing of foods not intended for special dietary uses, it is possible to achieve certain food characteristics only through the use of an artificial sweetener as a constituent of the food. When this situation exists, it is reasonable to consider the use of the artificial sweetener in such a food not to be for the purpose of reducing or maintaining body weight, or for use in the diet of diabetics: *Provided*, That no label reference is made to the caloric reduction or presence of the artificial sweetener in the food, other than the simple listing of the artificial sweetener as an ingredient. (WD–G–Moses, Q&A 21, 23–31; WD–G–Levine, Q&A 213, 214)

21. For the purposes of dietary evaluation and nutritional characteristics an infant should be considered to be a person 12 months of age or less. (Mickelsen, Tr. 2511; Lowe, Tr. 12, 568–70)

22. The term "serving" means that reasonable quantity of food suitable for or practicable of consumption as a part of a meal by an adult male engaged in light physical activity, or by an infant or child when the article purports or is represented to be for infant feeding or child consumption. (WD–G–Dawson, Q&A 17–20; Mickelsen, Tr. 2514, Exhibit P–718, P–723; WD–G–Gullberg, Q&A 42, 43; WD–G–Ross, Q&A 57)

23. Among dietitians and nutritionists it is customary to describe quantities of foods in units of measure thought to be readily understood by consumers such as teaspoonfuls, tablespoonfuls, cupfuls, and slices. (WD–G–Dawson, Q&A 21; WD–G–Gullberg, Q&A 42; WD–G–Ross, Q&A 58; Mickelsen, Tr. 2514)

24. The standard measuring cup is 8 fluid ounces or approximately 240 milliliters. A tablespoonful is the equivalent of 3 teaspoonfuls, approximately one-half fluid ounce, or about 15 milliliters. A teaspoon holds one-sixth fluid ounce or about 5 milliliters. (WD–G–Dawson, Q&A 22–25; WD–G–Gullberg, Q&A 44–47, 49)

25. Persons suffering from diabetes mellitus are known as "diabetics." (WD–G–Ricketts, Q&A 85; WD–G–Levine, Q&A 171; Exhibit P–1082)

26. There is no nutritional difference between a vitamin provided by a synthetic source and the same vitamin provided by a natural source, but the natural source may contain other ingredients which may limit the absorbability of the vitamin provided by the natural source. (Herbert, Tr. 9937–38, 9984, 10050)

27. A large number of dietary supplements on our domestic market advertise or otherwise call attention to the claim that their ingredients are "natural" or derived from "natural sources." (Swain, Tr. 234–477; Weissenberg, Tr. 6554–56, 8757–58; Exhibit P–35, P–40–43, P–54, P–66–68, P–70, P–74)

28. More than half of the people in the United States are likely to choose foods for special dietary uses that contain ingredients described as "natural" or derived from "natural sources" in the belief that "natural" foods are superior to "synthetic foods." (P–1151, pages B10–11, Q 16, Q 16a, Q 16b; WD–G–Perloff, A 44, 45, 46, 49)

29. For a considerable time, the labeling, promotion, and advertising of various foods offered for special dietary uses have contained statements claiming or suggesting that these products were adequate or effective, by virtue of their vitamin or mineral content, for the treatment, prevention, or mitigation of a large variety of diseases and symptoms. (Swain, Tr. 153, 157–8, 192–3, 199–200, 212–3, 224–5, 239, 254, 255, 264–72, 276–7, 286, 288–9, 314, 352, 354–6, 379, 385, 394, 396, 443–6, 453, 469–71, 478, 487–9; Weissenberg, Tr. 5819, 5980, 6017, 6027, 6049, 6152, 6193, 6347, 6416, 6436, 6443, 6450)

30. There is no rationale for allowing or encouraging the promotion and sale of dietary supplements of vitamins and/or minerals to the general American population for the purpose of treating, preventing, or curing diseases or symptoms. To the contrary, there is ample reason to discourage such methods of promoting foods for special dietary use. (Grollman, Tr. 1771–2; Mickelsen, Tr. 2520; Schweigert, Tr. 8233–4; Herbert, Tr. 9961; WD–G–Ross, Q&A 62; Hodges, Tr. 2994–5; Thiessen, Tr. 26,755–6; Briggs, Tr. 28,–750–1; Unglaub, Tr. 28,942–3; Wallerstein, Tr. 28,986–90; Mayer, Tr. 28,868, 28,892–8; Gershoff, Tr. 29,108–9)

31. Lay persons are incapable of determining, by themselves, whether they have, or are likely to develop, vitamin or mineral deficiencies. (Grollman, Tr. 1771–2, 1782; Herbert, Tr. 9961, 9979–80, 10,029; Unglaub, Tr. 28,942; Wallerstein, Tr. 28,989; Hodges, Tr. 2994–5; Mickelsen, Tr. 2520; Mayer, Tr. 28,892–3)

32. Since there are persons in the United States who are receptive to the suggestions that human ailments, to a great degree, can be prevented, treated, and cured by using vitamins and minerals, it is clear that representations or suggestions that certain symptoms, ailments, or diseases result from failure to ingest adequate amounts of vitamins and minerals will lead substantial numbers of the population to conclude that they must buy dietary supplements or other foods promoted for their vitamin or mineral qualities in order to prevent, cure, or treat certain diseases or symptoms. (WD–G–Perloff, Q&A 23–5; Weissenberg, Tr. 7738–9, 8474–7; WD–G–Gullberg; Q&A 14)

33. Literally true and scientifically accurate statements concerning the ultimate physiological result of vitamin or mineral deficiencies can mislead when made in connection with foods offered for special dietary use based upon their vitamin or mineral content. (Mayer, Tr. 28892–3; Gershoff, Tr. 29120)

34. Vitamin or mineral deficiencies are unrelated to the great majority of symptoms like tiredness, nervousness, and run-down condition. (Herbert, Tr. 10029)

35. When consumers read a label, promotional material, or advertising wherein a literally true statement is made, e.g., "Night blindness is caused by a lack of vitamin A," they may frequently conclude that the symptom will appear in them unless they use the product being promoted, or, on the basis that, even though they may not suffer from the specific symptoms described, the product will be generally good for improving their vision. (WD–G–Perloff, Q&A 30–31)

36. Vitamin and mineral deficiency are considered to be abnormal conditions resulting from inadequate consumption, absorption, transport, or utilization of one or more essential vitamins or minerals. The conditions are characterized by specific clinical signs, symptoms, and/or abnormalities observed in biochemical tests, and used together by physicians to establish the diagnosis. The term "subclinical" and similar ill-defined terms when used to refer to vitamin or mineral deficiencies, in the labeling of foods for special dietary use, are neither informative nor meaningful to consumers. (Mickelsen, Tr. 2537–9; WD–G–Schaefer, Q&A 23, 32–7; Herbert, Tr. 9880–5, 9984–5; Hodges, Tr. 2993–4, 3025; Grollman, Tr. 2023, 2252)

37. Scientifically it is inaccurate to state that the quality of soil in the United States causes abnormally low concentrations of vitamins or minerals in the food supply produced in this country. (Allaway, Tr. 12, 109; Herbert, Tr. 10,003)

38. There is no relationship between the vitamin content of foods and the chemical composition of the soil in which they are grown. (Allaway, Tr. 12,061, 10–063; Mickelsen, Tr. 2620)

39. Mineral nutrients in foods are not significantly affected by storage, transportation, cooking, and other processing. (Schweigert, Tr. 8200, 8223–4; Mickelsen, Tr. 2621)

40. While some vitamins are susceptible to partial destruction through the effects of heat, light, oxidation, and other physical and chemical reactions (Schweigert, Tr. 8200–8223), loss of nutrients from the ordinary effects of cooking, processing, transportation, and storage have not significantly impaired the nutritional qualities of food in the United States. There is no need or scientific justification for recommending, for example, the routine use of dietary supplements of vitamins and minerals to offset losses that occur as a result of these processes. (Schweigert, Tr. 8227–8, 8231; Mickelsen, Tr. 2527, 2642; Herbert, Tr. 9869–70)

41. It is reasonable to prohibit representation or suggestions in labeling, promotional material, or advertising of foods offered for special dietary use based on vitamin and mineral qualities, that imply that a dietary deficiency of vitamins or minerals exists or is threatened in the United States by virtue of loss of nutrients which occur from processing, transportation, storage, and cooking. (Schweigert, Tr. 8233–4)

42. Table salt has been fortified with iodine in the United States for many years. The usual level of fortification with potassium iodide is 0.01 percent by weight, which is equivalent to 0.0076 percent iodine (or about 0.01 percent iodine). This is commonly known as iodized salt. (Boehne, Tr. 2777–8; Herbert, Tr. 9948)

43. There is no necessity for iodized salt to contain on its label a statement of the percent or proportion of the recommended daily allowance for iodine provided in a specified serving, particularly since there is no specific serving size for salt and it is used in widely varying quantities. (Herbert, Tr. 9948; WD–G–Dawson, Q&A 29)

44. The use of dietary supplements of vitamins and minerals to ensure against a specific inadequacy of intake of these nutrients is a function clearly distinguished from the use of vitamin and mineral preparations for therapeutic purposes by the administration of large amounts of specific nutrients for the correction of disorders in humans, and the same product should not be used for both functions. (Grollman, Tr. 1680–82; Herbert, Tr. 9896; Hodges, Tr. 2937–40, 2970–71; WD–G–Harrison, Q&A 22; WD–3A–Sebrell, Q&A 44; WD–G–Schaefer, Q&A 36, 37).

45. It is often impractical to supply the iron needs of adult women with conventional foods, and iron supplementation is often advisable. (WD–3A–Sebrell, p. 17, Tr. 26088–89; Hodges, Tr. 3068–69; WD–46–Olson, pp. 10–11; WD–46–Wallerstein, pp. 12–13; WD–46–White, pp. 13–14; WD–46–Schwartz, pp. 6–7; WD–46–Margen, p. 7, Tr. 28713–14; Exhibit P–651, p. 59). Many women of childbearing age, particularly including those who are pregnant, ingest inadequate amounts of iron in the diets which they consume (WD–46–Mayer, pp. 14–17; Hodges, Tr. 6738; WD–65–Vitale, p. 5, Tr. 31914; WD–46–Unglaub, p–30; WD–46–Schwartz, pp. 6–10; WD–46–Wallerstein, pp. 9, 11–12, Tr. 28976; WD–46–Olson, p. 11; WD–46–Margen, p. 10; Goodhart, Tr. 30179; WD–46–Briggs, p. 27; WD–46–White, pp. 12–14; Krehl, Tr. 27218–19; Exhibit P–651, pp. 58–59). The iron intake of many adolescent girls and menstruating women is 10 milligrams or less each day. This value is consistent with the 1,500 to 2,000 calorie diet of sedentary women. In addition, the iron requirements of infancy and of the latter half of pregnancy are clearly in excess of what may be obtained from a conventional unfortified diet. (Exhibit 0–612–46, pp. 120–121).

PROPOSED CONCLUSIONS OF LAW

A. With respect to § 125.1 *Definitions and interpretations of terms:*

The Commissioner has carefully reviewed the history of the "special dietary" designation for foods to which nutrients have been added. At the time the original regulations relating to "special dietary" foods were being developed, it appeared reasonable, on the basis of nutrition knowledge, to classify fortified foods as special, and to require labeling under 21 CFR Part 125. Over the years the science of nutrition has moved forward, and the general requirement for nutrients, on a daily basis, have been better established. In addition, foods of all kinds are recognized as the preferred source of nutrients. The majority of those foods categorized as "special dietary foods" in the past for purposes of requiring nutrient labeling are in fact intended for consumption by the general population as conventional foods.

The development of general nutrition labeling regulations, available for use on all foods, has become of primary concern to all consumers, because of the ever increasing complexity of the conventional food supply. The use of the special dietary labeling under 21 CFR Part 125 for conventional foods with added nutrients can no longer be considered adequate to provide the consumer with a complete understanding of proper use of such foods in the diet. The Commissioner has, therefore, established that nutrition labeling (21 CFR 1.17) is the required form of labeling for foods with added nutrients, or for which the manufacturer makes nutritional claims or provides nutrition information on the label or in the labeling or advertising.

It is recognized that high levels of nutrient additions may occur for which labeling for special dietary uses is appropriate. Thus, a relationship between nutrition labeling (21 CFR 1.17) and the standard of identity for dietary supplements (21 CFR 80.1) has been established, providing that food with nutrients added up to levels of 50 percent of the U.S. Recommended Daily Allowance (U.S. RDA) will be labeled under 21 CFR 1.17, and that food with nutrients added at levels between 50 percent and 150 percent of the U.S. RDA or greater will be subject to the provisions of 21 CFR 80.1 and labeled under 21 CFR 1.17.

Within 3 broadly defined groups (infants and children under 4 years of age, adults and children 4 or more years of age, and pregnant or lactating women) values can be selected from the almost 390 RDA values, as well as information on the needs of each group for 4 nutrients for which there are no RDA's. In order to provide the consumer meaningful labeling it is necessary to provide a single level of RDA values for each of the above groups.

Selection of reasonable values for labeling purposes was done primarily by choosing the highest RDA value for each of the three groups. This was done so that the needs of all individuals in the age group would be included, recognizing that the needs of many would be surpassed by the selected value. Since there is no danger to health inherent in this approach, and it does not significantly affect the traditional concept of teaching consumers about the nutrient contribution of specific foods, the selection which is made is reasonable for the purpose stated.

The Commissioner realizes that legal challenge may be brought against the new approach to nutrition labeling in 21 CFR 1.17. If 21 CFR 1.17 is found invalid for any reason it will be necessary to resume the labeling of foods with added nutrients, or for which nutritional claims are made, under 21 CFR Part 125. The Commissioner is therefore keeping the record on this portion of the hearing open, for this limited purpose, in the event that it becomes necessary to amend this tentative order or to issue a supplemental tentative order to provide for labeling of this type pursuant to 21 CFR Part 125 in lieu of 21 CFR 1.17.

Accordingly, the Commissioner concludes, based on the foregoing statement in conjunction with the findings of facts herein published, that:

1. It is reasonable and necessary, in order to fully inform purchasers of the value of foods for special dietary uses, to define "special dietary use" as set forth in § 125.1(a).

2. It is reasonable and necessary, in order to fully inform purchasers of the value of foods for special dietary uses, to establish "recommended daily allowances" for essential nutrients as set forth in § 125.1(b).

3. The "recommended daily allowances" as set forth in § 125.1(b) are reasonable.

4. The definition of "artificial sweetener," as set forth in § 125.1(c), is reasonable.

B. With respect to § 125.2 *General label statements; dietary properties; value; placement:*

Over the years there have been a number of ingredients or products marketed as nutrients and nutritional supplements, which have not been shown to be essential in human nutrition. This point was discussed in considerable detail during the 1968–70 special dietary hearings held by the Food and Drug Administration. Among ingredients or products of this type are rutin, other bioflavonoids, para-aminobenzoic acid, inositol, and similar ingredients, products, and compounds. These ingredients or products have frequently been combined with vitamins and minerals or otherwise represented as a type of nutritional supplement. In these situations there is a false representation that these ingredients or products have nutritional value. The Commissioner has concluded that ingredients or products of this type may not properly make direct or implied nutritional claims, and that in no instances can these be represented in any way that suggests a nutritional value. Combining these products with added vitamins and/or minerals in any food, or adding these ingredients to any food for which nutrition labeling is used, or calling attention to these products in any manner which would be considered to imply some nutritional benefit, is inherently misleading. Labeling of such ingredients or products may not state that their usefulness in human nutrition has not been established, or otherwise disclaim dietary or therapeutic value, since such statements are also misleading. The Commissioner recognizes that there are individuals who desire to purchase ingredients or products of this type for various reasons. These individuals have a right to obtain these ingredients or products as long as they are truthfully labeled. Thus, ingredients or products of this type may properly be marketed as individual ingredients, or products, or mixtures thereof, provided no nutritional or dietary supplement claims are made.

Accordingly, the Commissioner further concludes, based on the foregoing statement in conjunction with the finding of facts herein published, that it is reasonform and necessary, in order to fully inform purchasers of the value of foods for special dietary uses, to require that the labels of such foods bear a statement as required and limited by § 125.2 as set forth in this tentative order.

C. With respect to § 125.3 *Label statements relating to vitamins and minerals*:

With the development of nutrition labeling (21 CFR 1.17) the use of special dietary labeling under 21 CFR Part 125 will be for all practical purposes limited to those articles which purport or are represented to supply a special dietary need that exists by reason of a physical or physiological condition, food represented for use as the sole item of the daily diet, and dietary supplements as provided for in 21 CFR 80.1.

The Commissioner recognizes there are foods which by their nature may contain nutrients in excess of 100 percent of the U.S. RDA per serving or reasonable daily intake. The Commissioner further recognizes the need for reasonable ranges for individual nutrients in dietary supplements above and below the U.S. RDA. The Commissioner further recognizes that departures from the U.S. RDA are appropriate for certain types or classes of foods for special dietary uses, e.g., chemically defined diets used in the dietary management of critically ill patients.

Accordingly, the Commissioner concludes, having considered the findings of fact and other relevant information, that it is reasonable and necessary, in order to fully inform purchasers of the value of foods for special dietary uses, to require that the labels of such foods, by reason of their vitamin or mineral content, bear a statement of the percentages of the recommended daily allowances for such vitamins and minerals. Nutrition labeling under 21 CFR 1.17 is not sufficiently precise for these special types of food.

TENTATIVE ORDER

Therefore, on the basis of the foregoing findings of fact and conclusions of law drawn therefrom: *It is ordered*, That the stay of effective date of §§ 125.1 through 125.3, promulgated December 14, 1966 (31 FR 15730), be ended, and that Parts 1, 3, and 125 of Title 21 of the Code of Federal Regulations be amended as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

§ 1.11 [Revoked]

1. The provisions of § 1.11 *Special dietary uses* are hereby revoked.

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

§ 3.9 [Revoked]

2. The provisions of § 3.9 *Label declaration of vitamin E in food for special dietary use* is hereby revoked.

§ 3.32 [Revoked]

3. The provisions of § 3.32 *Label declaration of vitamin B_{12} and folic acid in food for special dietary uses* is hereby revoked.

§ 3.46 [Revoked]

4. The provisions of § 3.46 *Interpretations of orders relating to dietary supplements; vitamin and mineral-fortified foods; foods for special dietary use* are hereby revoked.

PART 125—LABEL STATEMENTS CONCERNING DIETARY PROPERTIES OF FOOD PURPORTING TO BE OR REPRESENTED FOR SPECIAL DIETARY USES

5. The provisions of §§ 125.1, 125.2, and 125.3 are revised to read as follows:

§ 125.1 Definitions and interpretations of terms.

The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable with the following additions:

(a) The term "special dietary use" as applied to food (including dietary supplements) used by man means a particular use for which an article purports or is represented to be used, including but not limited to the following:

(1) Supply a special dietary need that exists by reason of a physical, physiological, or other condition, including but not limited to the conditions of convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, diabetes mellitus, or the need to control the intake of sodium. The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics.

(2) Supplying a vitamin, mineral, or other dietary property for use by man to supplement his diet by increasing the total dietary intake, except for foods for which nutrition labeling is used as required pursuant to § 1.17 of this chapter.

(3) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

(b) The term "U.S. Recommended Daily Allowance (U.S. RDA)" means the following daily amounts of the following vitamins and minerals:

Vitamins and minerals[1]	Unit of measurement	Infants and children under 4 years of age	Adults and children 4 or more years of age	Pregnant or lactating women
Vitamin A	International units	2,500	5,000	8,000
Vitamin D	do	400	400	400
Vitamin E	do	10	30	30
Vitamin C	Milligrams	40	60	60
Folic acid	do	0.2	0.4	0.8
Thiamine	do	0.7	1.5	1.7
Riboflavin	do	0.8	1.7	2.0
Niacin	do	9.0	20	20
Vitamin B_6	do	0.7	2.0	2.5
Vitamin B_{12}	Micrograms	3	6	8
Biotin	Milligrams	.15	0.3	0.3
Panthothenic Acid	do	5.0	10	10
Calcium	Grams	0.8	1.0	1.3
Phosphorus	do	0.8	1.0	1.3
Iodine	Micrograms	70	150	150
Iron	Milligrams	10	18	18
Magnesium	do	200	400	400
Copper	do	1.0	2.0	2.0
Zinc	do	8.0	15	15

[1] The following synonyms may be added in parentheses immediately following the name of the vitamin:

Vitamin	*Synonym*
Vitamin C	Ascorbic acid.
Folic acid	folacin.
Riboflavin	vitamin B_2.
Thiamine	vitamin B_1.

(c) In addition to the vitamins and minerals listed in paragraph (b) of this section, vitamin K and the minerals chlorine, potassium, sodium, sulfur, fluorine, and manganese are recognized as essential in human nutrition, but no U.S. Recommended Daily Allowance (U.S. RDA) has been established for these nutrients.

(d) The term "artificial sweetener" means a sweetening substance not used in normal metabolism as a source of calories.

(e) The term "infant" means a person not more than 12 months of age.

(f) The term "serving" means that reasonable quantity of food suited for or practicable of consumption as part of a

meal either by an adult male engaged in light physical activity, or by an infant or child when the article purports or is represented to be for infant feeding or child consumption. A label statement regarding a serving, as used in this part, shall be in terms of a convenient unit of such food or a convenient unit of measure that can be readily understood by purchasers of such food, e.g., a serving may be expressed in terms of slices, cookies, or wafers, or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls. A teaspoonful shall be considered to mean 5 milliliters (approximately ⅙ fluid ounce) in volume; a tablespoonful shall be considered to mean 15 milliliters (approximately ½ fluid ounce) in volume; and a cupful shall be considered to mean 240 milliliters (approximately 8 fluid ounces) in volume.

(g) The term "diabetic" means a person having diabetes mellitus.

(h) Any product containing more than the upper limit of the U.S. RDA of a vitamin or mineral is a drug, except for a food represented for use solely under medical supervision in the dietary management of specific diseases and disorders.

§ 125.2 General label statements; dietary properties; value; placement.

(a) If a food purports or is represented to be for any special dietary use, unless covered by other regulations, the principle display panel of its label shall bear a conspicuous statement of the usefulness of the food, limited to a listing of the dietary properties upon which such use is based: *Provided, however,* That if insufficient space is available on the principle display panel, the information panel may be used (21 CFR 1.8d), if such use is consistent with § 1.9 of this chapter. Such statement shall show the presence or absence of any substance, any alteration of the quantity or character of any constituent, and any other special dietary property of such food upon which such use is based.

(b) A food which purports or is represented to be a food for special dietary use shall be deemed to be misbranded under sections 201(n) and 403 (a) and (j) of the act (21 U.S.C. 321(n), 343 (a) and (j)), if its labeling bears any statement, vignette, or other printed or graphic matter that represents, suggests, or implies:

(1) That the food, because of the presence or absence of certain vitamins and/or minerals, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom, except that the label may state that the food is a source of an essential nutrient and that this nutrient is important for good nutrition and health, and except that this provision shall not apply to foods represented for use solely under medical supervision in the dietary management of specific diseases and disorders.

(2) That a diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) That the lack of optimum nutritive quality of a food, by reason of the soil on which that food is grown, is or may be responsible for an inadequacy or deficiency in the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of diets.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition. Ingredients of products such as rutin, other bioflavonoids, para-aminobenzoic acid, inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential in human nutrition may not be combined with vitamins and/or minerals, added to food labeled in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof: *Provided,* That the possibility of nutritional, dietary, or therapeutic value is not stated or implied, e.g., their labeling does not state that their usefulness in human nutrition has not been established and does not otherwise disclaim nutritional, dietary, or therapeutic value.

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin, or that there is a difference between vitamins naturally present and those that have been added.

§ 125.3 Label statements relating to vitamins and minerals.

(a) If a food purports or is represented to be for special dietary use because of vitamin or mineral properties, the label shall bear a statement of the percentage of the U.S. RDA of such vitamins and minerals, as set forth in § 125.1(b), suplied by such food when consumed in a specified quantity during a period of 1 day. The quantity specified shall be a reasonable quantity suitable for and practicable of consumption within 1 day. The order in which the nutrients appear on the label shall be in the order listed in § 125.1(b), except when other regulations indicate otherwise. Immediately preceding the declaration of vitamin and mineral content, the following heading shall be stated, "Percentage of U.S. Recommended Daily Allowances (U.S. RDA)". If such purported or represented special dietary use is for persons within one or more groups for which the recommended daily allowance is set, such statement shall include the percentage for each age group. When such proportion or percentage is a whole number and a fraction or a whole number and a decimal, it may be expressed as the whole number disregarding the fraction or decimal. The total quantity of vitamins or minerals in a food shall be no less than the amount declared, and no more than a reasonable amount above the declared quantity. Reasonable variations caused by heat, light, oxidation, storage, transportation, or unavoidable deviations in good manufacturing practice are recognized.

(b) The requirements of this section shall not apply to iodized salt, when the declared content of the iodine compound in the salt is equivalent to 0.01 percent by weight iodine.

Any interested person whose appearance was filed at the hearing may, on or before March 20, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6–88, 5600 Fishers Lane, Rockville, MD 20852, written exceptions thereto. Exceptions shall point out with particularity the alleged errors in the proposed findings of fact and tentative order, and shall contain specific references to the pages of the transcript of testimony and to the exhibits on which the exceptions are based. Exceptions and accompanying briefs should be submitted in quintuplicate.

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.73-997 Filed 1-18-73;8:45 am]

[21 CFR Parts 3, 20]

FROZEN DESSERTS

Mellorine, Parevine; Proposal To Establish Standards of Identity

The White House Conference on Food, Nutrition, and Health was held in December 1969. The final report of the conference made many recommendations regarding food standards promulgated under Section 401 of the Federal Food, Drug, and Cosmetic Act. Among these were recommendations:

1. That a standard of characterization for food should specify the characterizing properties or ingredients of the food, and perhaps establish a required minimum level for them, but should not specify other ingredients that may be used by chemical name.

2. That a complete statement of ingredients be required on every food label, including labels of food covered by Government standards.

3. That technical chemical designations be simplified to make the statement of ingredients more meaningful and understandable to consumers.

4. That informative generic names should be considered in place of the over simplified "imitation" label. The term "imitation" on product labels has erroneously been applied not only to new products that are inferior to the traditional foods they resemble, but also to new products that are equal or superior to traditional foods.

A vegetable fat frozen dessert resembling ice cream and known as "mellorine" was first marketed in Texas in 1942. Since that time 25 States have either established regulations for or in some other way allowed distribution of such frozen dessert products resembling ice cream. Included in this group of frozen desserts is the product known as "parevine," which is similar to mellorine but contains no milk or meat or milk or meat derived ingredients. Federal definitions and standards of identity have been estab-

lished for frozen desserts which do not permit fat or oil ingredients other than milkfat, and a formal statement of policy or interpretation (21 CFR 3.39) has been issued to require the name "imitation ice cream" on vegetable fat products made in semblance of ice cream. The conflicting provisions of regulations promulgated pursuant to the Federal Food, Drug, and Cosmetic Act with the various State regulations have had the effect of inhibiting the movement of these products in interstate commerce. Since mellorine and parevine now appear to be the common or usual names of these products, the Commissioner proposes to revoke § 3.39, and establish identity standards for these foods.

Other products which resemble ice cream, and which do not conform to either of the standards set forth below for mellorine and parevine, are theoretically possible. It is not the intention of the Commissioner of Food and Drugs, in proposing identity standards for mellorine and parevine, to preclude the manufacture of such frozen desserts under appropriately descriptive names. However, standards of identity for such products are not proposed at this time because the products do not yet appear to be significant items of commerce, as are mellorine and parevine.

Accordingly, it is proposed that:

§ 3.39 [Revoked]

1. Part 3 be amended by revoking § 3.39.

2. Part 20 be amended by adding two new sections to provide for standards of identity for mellorine and parevine, as set forth below:

§ 20.— Mellorine; identity.

(a) *Description.* Mellorine is the frozen food produced by freezing, while stirring, a pasteurized mix consisting of safe and suitable ingredients, including but not limited to nonfat milk solids and animal or vegetable fat, only part or which may be milkfat. Mellorine contains not less than 6.0 percent by weight of fat, and nonfat milk solids from milk, skim milk or buttermilk in such quantity that the milk protein contributed thereby is not less than 3 percent by weight of the finished food. Mellorine is sweetened with nutritive sweetener and is flavored. Mellorine contains not less than 1.6 pounds of total solids to the gallon and weighs not less than 4.5 pounds to the gallon.

(b) *Fortification.* Vitamin A is present in a quantity which will insure that 40 International Units (I.U.) are available for each gram of fat in mellorine. This requirement will be deemed to have been met if reasonable overages, within limits of good manufacturing practice, are added to insure that the required vitamin level is maintained throughout the expected shelf life of the food under customary conditions of distribution.

(c) *Definitions.* For the purposes of this section:

(1) A pasteurized mix is one which has been heated uniformly to one of the temperatures specified in the table below, and held continuously at or above that temperature for the specified time.

Temperature	*Time*
155° F.	30 minutes
175° F.	25 seconds

(2) Safe and suitable ingredients are functionally suitable substances that are not food additives or color additives within the meaning of section 201 (s) or (t) of the Federal Food, Drug, and Cosmetic Act, or if they are addivites as so defined, they are used in conformity with regulations established pursuant to section 409 or 706 of the act. They are used only in such amounts as are reasonably necessary to accomplish their intended effect.

(d) *Methods of Analysis.* Fat content shall be determined by the method contained in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970—"Fat, Roese-Gottlieb Method—Official Final Action," section 16.228.[1]

(e) *Nomenclature.* The name of the food is "mellorine." The food shall be labeled in compliance with Part 1 of this chapter. For the purposes of § 1.12 of this chapter: (1) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent, as that term is defined in § 22.1(c) of this chapter.

(ii) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished mellorine, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus mellorine, 6 percent in the case of berry or cherry mellorine, and 10 percent in the case of mellorine prepared with other fruits.

(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used is such that, in relation to the finished mellorine, the weight of the nut meats is less than 2 percent.

(iv) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (e) (ii) or (iii) of this section. For example, if a combination mellorine contains less than 5 percent of bananas and less than 1 percent of almonds it would be "Artificially flavored banana-almond mellorine." However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be "Banana-almond flavored mellorine."

(2) If two or more flavors of mellorine are distinctively combined in one package, e.g., "Neapolitan" mellorine, the applicable provisions of this paragraph shall govern each flavor of mellorine comprising the combination.

(f) *Label declaration.* The common name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 1 of this chapter and nutrition labeling shall be presented in conformity with the requirements prescribed in § 1.17 of this chapter, except that:

(1) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as "skim milk."

(2) Concentrated milk, dried milk, and reconstituted milk prepared by addition of water to milk or dried milk may be declared as "milk."

(3) Sweetcream buttermilk, concentrated sweetcream buttermilk, and dried sweetcream buttermilk may be declared as "buttermilk."

(4) Cheese whey, concentrated cheese whey, and dried cheese whey may be declared as "whey."

(5) Cream, dried cream, plastic cream (sometimes known as concentrated milkfat), and anhydrous milkfat may be declared as "cream."

§ 20.— Parevine.

(a) *Description.* Parevine is the frozen food produced by freezing, while stirring, a pasteurized mix consisting of safe and suitable ingredients including, but not limited to, vegetable fat and sources of egg or vegetable protein; but excluding milk, meat, and any milk or meat derived ingredients. Parevine contains not less than 6 percent by weight of fat and not less than 3 percent by weight of protein. Parevine is sweetened with nutritive sweetener and is flavored. Parevine contains not less than 1.6 pounds of total solids to the gallon and weighs not less than 4.5 pounds to the gallon.

(b) *Fortification.* Vitamin A is present in a quantity which will insure that 40 International Units (I.U.) are available for each gram of fat in parevine. This requirement will be deemed to have been met if reasonable overages, within limits of good manufacturing practice, are added to insure that the required vitamin level is maintained throughout the expected shelf life of the food under customary conditions of distribution.

(c) *Definitions.* For the purposes of this section:

(1) A pasteurized mix is one which has been heated uniformly to one of the temperatures specified in the table below, and held continuously at or above that temperature for the specified time.

Temperature	*Time*
155° F.	30 minutes
175° F.	25 seconds

(2) Safe and suitable ingredients are functionally suitable substances that are not food additives or color additives

[1] Copies may be obtained from Association of Official Analytical Chemists, Post Office Box 540, Benjamin Franklin Station, Washington, DC 20044.

within the meaning of section 201(s) or (t) of the Federal Food, Drug, and Cosmetic Act, or if they are additives as so defined, they are used in conformity with regulations established pursuant to section 409 or 706 of the act. They are used only in such amounts as are reasonably necessary to accomplish their intended effect.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[1]

(1) Fat content—"Fat, Roese-Gottlieb Method—Official Final Action," section 16.228.

(2) Protein content—"Nitrogen—Official Final Action, Kjeldhl Method," section 16.226.

(e) *Nomenclature.* The name of the food is "parevine." The food shall be labeled in compliance with Part 1 of this chapter. For the purposes of § 1.12 of this chapter:

(1) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent, as that term is defined in § 22.1(c) of this chapter.

(ii) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished parevine, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus parevine, 6 percent in the case of berry or cherry parevine, and 10 percent in the case of parevine prepared with other fruits.

(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used is such that, in relation to the finished parevine, the weight of the nut meats is less than 2 percent.

(iv) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (e) (ii) or (iii) of this section. For example, if a combination parevine contains less than 5 percent of bananas and less than 1 percent of almonds it would be "Artificially flavored banana-almond parevine." However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be "Banana-almond flavored parevine."

(2) If two or more flavors of parevine are distinctively combined in one package, e.g., "Neapolitan" parevine, the applicable provisions of this paragraph shall govern each flavor of parevine comprising the combination.

[1] Copies may be obtained from Association of Official Analytical Chemists, Post Office Box 540, Benjamin Franklin Station, Washington, DC 20044.

(f) *Label declaration.* The common name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 1 of this chapter and nutrition labeling shall be presented in conformity with the requirements prescribed in § 1.17 of this chapter.

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 403, 701, 52 Stat. 1046, as amended, 1047, as amended, 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 343, 371) and in accordance with authority delegated to the Commissioner (21 CFR 2.120), interested persons are invited to submit their views in writing (preferably in quintuplicate) regarding this proposal on or before March 20, 1973. Such views and comments should be addressed to the Hearing Clerk, Department of Health, Education, and Welfare, Room 6–88, 5600 Fishers Lane, Rockville, MD 20852, and may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

NOTE: Incorporation by reference provisions approved by the Director of the Federal Register, January 15, 1973.

[FR Doc.73-995 Filed 1-18-73;8:45 am]

[21 CFR Parts 18, 19, 20, 27, 45]

CERTAIN STANDARDIZED FOODS

Nutrition Labeling

The Commissioner of Food and Drugs is promulgating elsewhere in this issue of the FEDERAL REGISTER a new § 1.17, establishing nutrition labeling for all foods to which vitamins or minerals are added or for which the manufacturer wishes to include information about nutrient content in labeling or advertising. The Commissioner has concluded that standardized foods, to which the addition of nutrients is optional or mandatory, should be labeled to comply with the new § 1.17 rather than the provisions of 21 CFR Part 125, which has been the case in the past. The new regulation automatically has this effect.

Some existing standards for enriched foods specifically require labeling in compliance with 21 CFR Part 125. To clarify the situation, the Commissioner has concluded that these standards should themselves be amended to refer directly to the new § 1.17 so that no confusion can arise.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 403, 701(a), 52 Stat. 1040–1042, 1046–1048, and 1055; 48, 21 U.S.C. 321, 341, 343, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend the following listed provisions in existing standards of identity for foods by replacing each reference to 21 CFR Part 125 with a reference to 21 CFR 1.17, e.g., the reference in § 27.127(e)(1) to "for foods which purport to be or are represented for special dietary uses by regulations promulgated pursuant to section 403(j) of the Federal Food, Drug, and Cosmetic Act" will be changed to read "in § 1.17":

STANDARDS NOW IN EFFECT

21 CFR citation	Subject matter
1. § 18.545(d)	Nonfat dry milk fortified with vitamins A and D.
2. § 19.513(f)	Low sodium colby cheese.
3. § 27.54(c)(2)	Canned pineapple juice.
4. § 27.60(c)(2)(iv)	Canned prune juice.
5. § 27.80(d)(7)	Canned applesauce.
6. § 45.1(b)(2)(v)	Oleomargarine, margarine.

FINAL ORDERS NOT YET CONFIRMED

21 CFR citation	Subject matter	FR citation
1. § 27.158(e)	Orange juice drink	(37 FR 5224)

PROPOSED STANDARDS

1. § 18.2(f)	Milk	(37 FR 18392)
2. § 18.520(f)	Evaporated milk	(37 FR 18392)
3. § 18.525(f)	Concentrated milk	(37 FR 18392)

STANDARDS THAT HAVE BEEN STAYED

1. § 27.120(f)	Orange juice-drink	(33 FR 10713)
2. § 27.125(f)	Canned pineapple-grapefruit juice-drink.	(33 FR 10713)
3. § 27.126(g)	Canned fruit nectars	(33 FR 10713)
4. § 27.127(e)	Cranberry juice cocktail.	(33 FR 10088)
5. § 27.128(c)	Artificially sweetened cranberry juice cocktail.	(33 FR 10088)

In those food standards in which there is presently no reference to 21 CFR Part 125, although enrichment is provided and special dietary food labeling has uniformly been required, e.g., enriched bread and enriched flour, 21 CFR 17.2 and 15.10, it is unnecessary to make any change because the terms of the new § 1.17 automatically make it applicable to such products.

Interested persons may, on or before February 20, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, room 6–88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.73-994 Filed 1-18-73;8:45 am]

[21 CFR Part 80]

DIETARY SUPPLEMENTS OF VITAMINS AND MINERALS

Definition, Identity, and Label Statements; Proposed Findings of Fact, Conclusions, and Tentative Order Following a Public Hearing

In the matter of establishing a definition and standard of identity for dietary supplements of vitamins and minerals:

HISTORY

1. On the initiative of the Commissioner of Food and Drugs, a notice of proposed rule making in the above-identified matter was published in the FEDERAL REGISTER of June 20, 1962 (27 FR 5815), and numerous comments were received in response thereto. Subsequently, orders were published in the FEDERAL REGISTER of June 18, 1966 (31 FR 8521 et seq.), to become effective December 15, 1966, deleting § 1.11 (21 CFR 1.11), exempting from labeling requirements certain artificially sweetened foods (21 CFR 5.5), establishing definitions and standards of identity for dietary supplements of vitamins and minerals and for vitamin- and mineral-fortified foods (21 CFR Part 80), and revising the regulations for the labeling of food for special dietary uses (21 CFR Part 125).

2. During the 30-day period provided by the order of June 18, 1966, objections and requests for a public hearing were filed. Consequently, an order was published in the FEDERAL REGISTER of December 14, 1966 (31 FR 15730), staying the effective date of § 5.5, Part 80, and Part 125, as published in the FEDERAL REGISTER of June 18, 1966, and staying the effective date of the deletion of § 1.11. The order published in the FEDERAL REGISTER of December 14, 1966, gave notice that a public hearing would be held on the basis of the objections received and set forth the issues to be decided at the hearing. Since the order also contained amendments to the provisions of Parts 80 and 125 published in the FEDERAL REGISTER of June 18, 1966, an additional period of 30 days was provided for the filing of objections by persons adversely affected. Numerous letters objecting to the amendments and requesting a public hearing were received; however, no substantive issues not already stated in the order of December 14, 1966, were raised by these objections. A correction of a printer's error in the order of December 14, 1966, was published in the FEDERAL REGISTER of December 21, 1966 (31 FR 16312).

3. Also published December 14, 1966 (31 FR 15746), was a notice proposing that § 80.2, the definition and standard of identity for vitamin- and mineral-fortified foods, which was established by the order of June 18, 1966, and amended and stayed by the order of December 14, 1966, be amended by adding to the table in paragraph (c) the following classes of food: (1) Frozen dessert products (containing vegetable fat in lieu of butter fat) made in semblance of ice cream or ice milk; (2) milk fortifiers; (3) and meal substitutes.

4. The comments received in response to the proposal of December 14, 1966, were considered and an order was subsequently published in the FEDERAL REGISTER of April 8, 1967 (32 FR 5736), amending § 80.2 to add the additional classes of food. In response to that order, several objections and requests for a public hearing were received; however, no substantive issues were raised that were not already set forth in the order of December 14, 1966.

5. A notice was published in the FEDERAL REGISTER of April 2, 1968 (33 FR 5268), scheduling a hearing to begin May 21, 1968, and a prehearing conference to begin May 7, 1968. The notice also designated Mr. David H. Harris as the Hearing Examiner for these proceedings, and notice that he was appointed a hearing examiner was published in the FEDERAL REGISTER of May 4, 1968 (33 FR 6828).

6. The hearing was convened as scheduled May 21, 1968, and recessed the same day to permit continuation of prehearing conferences. Notice was given in the FEDERAL REGISTER of June 13, 1968 (33 FR 8679), that the hearing was being reconvened June 20, 1968. The hearing was reconvened as scheduled and continued for almost 2 years, closing on May 14, 1970.

7. The taking of evidence with reference to infant foods was closed October 14, 1969. Pursuant to 21 CFR 2.96, and limited to the infant food portion of the proceedings, the Hearing Examiner submitted his report and certified the record together with his report to the Commissioner of Food and Drugs. This Hearing Examiner's Report, dated August 26, 1970, is part of the public record (Docket No. FDC–78) on file with the Hearing Clerk, Department of Health, Education, and Welfare, room 6–88, 5600 Fishers Lane, Rockville, MD 20852.

8. The Hearing Examiner sbsequently submitted his report of the entire proceedings, except for the previously submitted portion on infant foods, and certified the associated record together with his report to the Commissioner of Food and Drugs. This Hearing Examiner's Report, dated January 25, 1971, is part of the public record (Docket No. FDC–78) and is also on file with the Hearing Clerk.

9. After review of the Hearing Examiner's report and related material on the infant food portion of the proceedings, the Commissioner published in the FEDERAL REGISTER of October 29, 1970 (35 FR 16737), proposed findings of fact, proposed conclusions, and a tentative order on label statements relating to infant foods, and provided a 30-day period for filing of written exceptions. After review of comments received, and further review of the Hearing Examiner's Report and related material, several changes were made in the tentative order, and the final order on label statements relating to infant foods (21 CFR 125.5) was published in the FEDERAL REGISTER of December 10, 1971 (36 FR 23553), with an effective date 90 days from the date of publication.

10. After review of the Hearing Examiner's report and related material on the portion of the proceedings concerning vitamin- and mineral-fortified foods, the Commissioner concluded that it would be in the public interest to develop regulations for such foods utilizing the approach of establishing nutritional quality guidelines for certain classes of foods, including those to which vitamins and/or minerals may be added. These guidelines may replace the approach of developing standards of identity for these foods as originally proposed in the form of 21 CFR 80.2. A notice of proposed rule making on nutritional quality guidelines was published in the FEDERAL REGISTER of December 23, 1971 (36 FR 24822). In that notice, the Commissioner proposed to amend Chapter I by adding a new Part 100 for nutritional quality guidelines for foods, defined general principles (proposed 21 CFR 100.1), and proposed the first nutritional quality guideline, in this case for pre-cooked frozen convenience "heat and serve" dinners (proposed 21 CFR 100.20). The Commissioner is deferring final action on 21 CFR 80.2 until experience is gained under 21 CFR Part 100.

11. In this issue of the FEDERAL REGISTER, the Commissioner has published the following proposals, tentative orders, and regulations that relate to other sections of special dietary labeling and nutrition labeling as follows:

(a) Nutrition labeling. (§ 1.17)

(b) Food label information panel. (§ 1.8d)

(c) Food fat labeling. (§ 1.18)

(d) Special dietary food labeling. (§§ 125.1, 125.2, and 125.3)

(e) Food standard labeling changes.

(f) Uniform effective date for food labeling changes.

LIMITED SCOPE OF THIS ACTION

12. This document pertains only to that portion of this matter concerning the definition, standard of identity, and label statements of dietary supplements of vitamins and minerals. The content of this document reflects the following needs as developed by the public hearing and related historical events:

(a) That dietary supplements as defined should be based on modern human nutrition knowledge.

(b) That potentially toxic quantities of individual nutrients, insignificant quantities of individual nutrients, and gross nutrient imbalances and omissions should be avoided in dietary supplements.

(c) That a fully informative labeling system is required.

(d) That expiration dating is required.

13. To further clarify the limited scope of this action a number of additional points require comment:

(a) The purpose of dietary supplements of vitamins and minerals is to provide reasonable assurance that the total daily intakes of essential vitamins and/or minerals are adequate when doubt of adequacy may exist on the basis of the diet alone. Dietary supplements are for general supplementation of the diet. They are not designed for the treatment or clinical management of nutritional diseases or disorders.

(b) This action does not apply to natural substances, which by their nature are good sources of specific vitamins and/or minerals, except when used as a source of specific vitamins and/or minerals in dietary supplements. Although not marketable as dietary supplements except as indicated, such natural sub-

stances may be marketed as conventional foods, subject to nutritional labeling (21 CFR CFR 1.17) pertaining thereto. Other foods to which this action does not apply are described in the tentative order contained in this document.

(c) This document establishes lower and upper limits for each individual vitamin and mineral which may be present in the specified daily quantities of dietary supplements of vitamins and minerals. All of the provisions of this document are in turn subject to the provisions of 21 CFR Part 125, which define the term "special dietary use", establish the U.S. Recommended Daily Allowances (U.S. RDA's) specified by the U.S. Government in terms of nutrients and quantities of nutrients, and provide specific instructions on the general label statements permitted on foods for special dietary use under § 125.1 *Definitions and interpretations of terms;* § 125.2 *General label statements; dietary properties; value; placement;* and § 125.3 *Label statements relating to vitamins and minerals.*

(d) The tentative order contained in this document requires that the individual nutrients in dietary supplements be listed on the label in a specific order. Placing a specific nutrient or nutrients in a prominent position in a list of nutrient components can imply to the consumer a degree of relative importance for the specific nutrient or nutrients so placed. Such a prominent position for any specific nutrient is not scientifically sound in a dietary supplement of vitamins and/or minerals.

Having considered the evidence received at the hearings, the hearing examiner's report, and all the exceptions and written arguments which were filed, the Commissioner, pursuant to the Federal Food, Drug and Cosmetic Act (secs. 401, 403(j), 701(e), 52 Stat. 1046 as amended, 1048, 1055 as amended; 21 U.S.C. 341, 343(j), 371(e)) and under authority delegated to him (21 CFR 2.120), proposes the following findings of fact, conclusions of law, and tentative final order:

PROPOSED FINDINGS OF FACT [1]

1. The hearings have shown that there is a need to establish a definition for dietary supplements, and to describe what is a rational composition for dietary supplements in terms of the vitamins and minerals present, and the quantities allowed.

2. The apparent appeal to consumers which results from the addition of vitamins and minerals to food articles, with concurrent promotion calling attention to this fact, has resulted in ever increasing amounts, qualitatively and quantitatively, of these nutrients being added to various foods (Weissenburg, Tr. 8569–8570; Exhibit P–1151, page C1). In many cases, foods, particularly some cereal products, have become the equivalent of multivitamin/multimineral dietary supplements in terms of their added nutrient contents (Weissenberg, Tr. 8584; WD–G–Gullberg, Q&A 35).

3. The establishment of a standard of identity and quantitative limits for the nutrient ingredients in dietary supplements will reduce consumer confusion concerning choice of dietary supplements by insuring a basically rational formula for all products (Mayer, Tr. 28868; WD–G–Gullberg, Q&A 31).

4. Dietary supplements are articles purporting to be or represented for special dietary use by man to supplement his diet by increasing the total dietary intake of vitamins and/or minerals. They may be prepared as tablets, capsules, pills, wafers, or similar uniform units, and/or in powder, granular, flake or liquid form (Grollman, Tr. 1660; Mickelsen, Tr. 2421–2424; Hodges, Tr. 2874; Herbert, Tr. 9859; Garrett, Tr. 10943; WD–G–Ross, Q&A 14). The proper use of dietary supplements of vitamins and/or minerals is for short-term correction of specific inadequacy of intake (Hodges, Tr. 2874–2875; Herbert, Tr. 9860, 9922–9923). They are not intended for therapeutic use for the correction of disorders in humans by the administration of large amounts of specific nutrients (Grollman, Tr. 1680–1682; Herbert, Tr. 9896; Hodges, Tr. 2937–2940, 2970–2971; WD–G–Harrison, Q&A 22; WD–3A–Sebrell, Q&A 44; WD–G–Schaefer, Q&A 36, 37).

5. Vitamins are organic substances, present in foods, which are essential for the maintenance of human life and the activity of the cells of the body (Grollman, Tr. 1624–1625; WD–3A–Sebrell, Q&A 4). These include vitamins A, D, E, K, C (ascorbic acid), B_1 (thiamine), B_2 (riboflavin), B_6, and B_{12}, niacin, folic acid (folacin), biotin, and pantothenic acid (Exh. P–651; Grollman, Tr. 1625–1627).

6. Essential mineral nutrients include the inorganic elements calcium, phosphorus, iodine, iron, magnesium, copper, zinc, sodium, potassium, and manganese. They are needed by the human body in varying amounts, and are utilized in a variety of metabolic processes (WD–3A–Sebrell, Q&A 4).

7. The sale and use of vitamin/mineral preparations in the United States are extensive, running into hundreds of millions of dollars annually in wholesale bulk value, and involve three-fourths of American households (Exh. P–735; Exh. P–1151, pages B1 and B2). The majority of such preparations differ qualitatively and quantitatively from each other, presenting a bewildering variety to the consumer (Weissenberg, Tr. 5998, 6551–6552, 8752–8756; WD–G–Gullberg, Q&A 14, 26; Exhibits P–2, P–3, P–8, P–9, P–40–42, P–47, P–51–54, P–57–59, P–61–70, P–72–74, P–76–78, P–80–153, P–156–163, P–165–174, P–188, P–194–349, P–398, P–399, P–400, P–402–404, P–468, P–471, P–564, P–567, P–575–579, P–582–594, P–596–597, P–599, P–600, P–613).

8. Many dietary supplements are nutritionally irrational, in that they provide quantitative levels and qualitative combinations of nutrients for which no human individual need could possibly exist, if the products are used only as dietary supplements (Grollman, Tr. 1683 (Exhibit P–84), 1686 (Exhibit P–89), 1688 (Exhibit P–94), 1691 (Exhibit P–95), 1696 (Exhibit P–102), 1699 (Exhibit P–113), 1701–1702 (Exhibit P–113), 1707–1709 (Exhibit P–124), 1713 (Exhibit P–157), 1714 (Exhibit P–158); Mickelsen, Tr. 2447–2447A (Exhibit P–166), 2448–2450 (Exhibit P–168), 2451–2452 (Exhibit P–169), 2455–2457 (Exhibit P–171); Hodges, Tr. 2942 (Exhibit P–183); Herbert, Tr. 9898–9899 (Exhibit P–232); Weissenberg, Tr. 6553–6554; WD–G–Gullberg, Q&A 26; Exhibits P–588, P–595). Lay persons are incapable of determining, by themselves, whether they have or are likely to develop vitamin or mineral deficiencies (Grollman, Tr. 1771–2, 1782; Herbert, Tr. 9961, 9979–80, 10,029; Unglaub, Tr. 28,942; Wallerstein, Tr. 28,989; Hodges, Tr. 2994–5; Mickelsen, Tr. 2520; Mayer, Tr. 28,892–3).

9. Although approximately 20 percent of the users of dietary supplements of vitamins and minerals actually use those articles to supplement or balance their diet, more than 40 percent of those persons admit they have no idea which vitamins or minerals, if any, are not sufficiently supplied by their diet (Exhibit P–1151, page B4, Q&A 4b).

10. Certain basic vitamins and/or minerals should be included in all articles offered as multivitamin and/or multimineral supplements. The remaining group of appropriate vitamins and/or minerals are considered to be scientifically optional for inclusion (Herbert, Tr. 9880–9882). The mandatory group of vitamins and/or minerals found in multivitamin and/or multimineral supplements should include all those listed in the table entitled "Recommended Daily Dietary Allowances, Revised 1968" in publication 1694 of the National Academy of Sciences (WD–43–Filer, pp. 19–20; WD–33–Coursin, p. 23; WD–33–Emerson, p. 9; WD–33–Brin, pp. 23–24; WD–33–Krehl, pp. 8–9, Tr. 27216–27217, 27255–27256; WD–33–Horwitt, pp. 12–14; Hodges, Tr. 2878–2879, 2945–2946, 6813, 7007).

11. Many dietary supplements contain such high amounts of nutrients that they are appropriate only for therapeutic use, for persons already in a deficiency state (Hodges, Tr. 2939–40). Some of these contain potentially toxic amounts of certain vitamins (Herbert, Tr. 9891; Grollman, Tr. 1711; Exhs. P–113, P–183, P–594). There is a sound scientific basis for establishing quantitative maximums on the nutrient ingredients in a dietary supplement (Herbert, Tr. 9900–9904; WD–G–Ross, Q. & A. 17, 18; WD–G–Harrison, Q. & A. 22). This is based on the rapid excretion of excesses of certain nutrients without benefit to the consumer, as well as on the potential problems of toxicity or nutritional imbalances due to excessive ingestion of certain nutrients

[1] The abbreviations in the citations are:
Tr.—For transcript pages of the hearing.
P.—For exhibits introduced by the Government, the proponent.
O.—For exhibits introduced by opponents.
WD–G—For written direct testimony by a witness for the Government.
WD–3A—For written direct testimony by a witness for the designated opponent (e.g. "3A").
Q&A—Question and answer.

(Grollman, Tr. 1666–1669; Herbert, Tr. 9861–9862; Mickelsen, Tr. 2433–2434; WD–3A–Sebrell, Q. & A. 24, 25; Polack, Tr. 4954–4955; Exh. P–1142).

12. Some dietary supplements contain so little of a named nutrient as to be insignificant in human nutrition (Swain, Tr. 233, 488; Grollman, Tr. 1695–1696 (Exh. P–102); Mickelsen, Tr. 2448 (Exh. P–167), 2451 (Exh. P–169), 2456 (Exh. P–171), 2469 (Exh. P–173); Hodges, Tr. 2935 (Exh. P–180); WD–G–Gullberg, Q&A 26). There is a sound scientific basis for establishing quantitative minimums on the nutrient ingredients for dietary supplements since only substantial amounts of nutrients should be represented for purposes of dietary supplementation (Herbert, Tr. 9867; WD–G–Harrison, Q&A 24; Boehne, Tr. 2764; WD–3A–Sebrell, Q&A 26, 27, 39).

13. Certain dietary supplements are objectionable because they must be taken in large numbers of units for the user to get the designated amounts of the nutrients involved (Grollman, Tr. 1685 (Exhibit P–89); Hodges, Tr. 2936 (Exhibit P–180); Exhibits P–179, P–359, P–368, P–383, P–395). In establishing a standard of identity for dietary supplements it is medically and pharmacologically sound to establish a standard of identity for dietary supplements on the basis of units suitable for and practical of consumption in one day (Grollman, Tr. 1661; Hodges, Tr. 2956).

14. There are demonstrable distinctions among the nutritional requirements of infants and young children, and pregnant or lactating women, as compared to the nutritional requirements of adults (Michelsen, Tr. 2424–2427; Grollman, Tr. 1665; Hodges, Tr. 2877–2878; Herbert, Tr. 9944; WD–3A–Sebrell, Q&A 15, 16, 19 and 28; WD–G–Ross, Q&A 23; Boehne, Tr. 2741–2759).

15. There is scientific or medical justification for selecting an age separation at 4 years of age for the purpose of establishing a basis for dietary supplements (WD–33–Krehl, pp. 5–8; WD–33–Emerson, pp. 4–5; WD–43–Filer, p. 21). The recommended daily dietary allowances of the Food and Nutrition Board, NAS–NRC, for 2- to 3-year-olds can safely be used by infants and 1- to 2-year-olds, and the maximum values for the under 4-year-old group can be used for all infants and children under 4 years of age (WD–33–Krehl, pp. 6–7; Hodges, Tr. 2, 877–8; WD–43–Graham; and WD–43–Filer, p. 21).

16. The "Recommended Dietary Allowances," revised periodically by the Food and Nutrition Board of the National Research Council, National Academy of Sciences, represent established nutrient levels that are quantitatively high enough to provide for the adequate intake of essential nutrients under the wide variety of conditions that exist in this country for essentially all of the normal healthy persons in the United States. Furthermore, these levels are reviewed, discussed, and accepted by numerous scientists and, therefore, are considered to be extremely reliable. (Hodges, Tr. 2880, 2919, 2964–65; Grollman, Tr. 1670, 1763; Mickelsen, Tr. 2438–39; Herbert, Tr. 9865–67; WD–G–Harrison, Q&A 23; Schweigert, Tr. 8257, 8260; WD–G–Gullberg, Q&A 19; Exhibit P–651; Sebrell, Tr. 26, 181).

17. Publication No. 1694 of the National Academy of Sciences entitled "Recommended Dietary Allowances, Seventh Revised Edition, 1968, A Report of the Food and Nutrition Board, National Research Council," and subsequent editions, should be used as the source of authentic and reliable information on which to base recommended daily allowances of nutrients (WD–3A–Semrell, Q&A 9, 10, 18, 19, Tr. 26181; Hodges, Tr. 2917; Herbert, Tr. 9865; WD–G–Harrison, Q&A 14, 23, 26, 27; WD–G–Ross, Q&A 65).

18. Recommended dietary allowances adapted from publication 1694 of the National Academy of Sciences are sufficiently above the average requirement for particular nutrients to cover the needs of between 95 percent and 99 percent of the normal healthy population (Hodges, Tr. 7083; WD–46–Olsen, page 7, Tr. 29466–67; Jukes, Tr. 28688; Briggs, Tr. 28761; Mayer, Tr. 28865–66; Stokstad, Tr. 26742; Goodhart, Tr. 30169–70; Stare, Tr. 29280; WD–G–Ross p. 5).

19. The identity and levels of nutrients in the NAS–NRC Recommended Dietary Allowances are extremely reliable since they are reviewed and discussed by large numbers of scientists and brought up for revision approximately every 5 years (Mickelsen, Tr. 2438–2439); Hodges, Tr. 2880; Sebrell, Tr. 26181). They are the best basis on which to establish a standard of identity for dietary supplements of vitamins and minerals in the United States (Grollman, Tr. 1670; Mickelsen, Tr. 2438; Herbert, Tr. 9864–9865; WD–3A–Sebrell, Q&A 5–7; Sebrell, Tr. 26181; WD–G–Ross, Q&A 19). Publication 1694 of the National Academy of Sciences, entitled "Recommended Dietary Allowances, Seventh Revised Edition, 1968, A Report of the Food and Nutrition Board, National Research Council" should be used as the source of authentic and reliable information on which to base a standard of identity for dietary supplements of vitamins and minerals (Exhibit P–651). Values for essential nutrients (to be designated as "U.S. Recommended Daily Allowances (U.S. RDA's)") may reasonably be derived from the table and sections in the text of this publication (WD–3A–Sebrell, Q&A 15).

20. The human body has the capacity to store varying amounts of almost all vitamins as reserves to be drawn upon when needed (Mickelsen, Tr. 2436). Fat-soluble vitamins, particularly vitamins A and D, are readily stored for relatively long periods of time, while excesses of the water-soluble vitamins are excreted more rapidly (Grollman, Tr. 1628–1629; Mickelsen, Tr. 2645; WD–3A–Sebrell, Q&A 4). The excessive ingestion of the fat-soluble vitamins A and D, because of their relatively high retention by the human body, poses a potential danger of toxicity (Mickelsen, Tr. 2644–2645; Hodges, Tr. 2956; WD–G–Ross, Q&A 18; WD–G–Harrison, Q&A 22; Herbert, Tr. 9891).

21. The nutrients which are scientifically appropriate for inclusion in dietary supplements in the United States are (1) the vitamins A, C, D, E, folic acid, niacin, riboflavin, thiamine, B_6, B_{12}, biotin, and pantothenic acid; and (2) the minerals calcium, phosphorus, iodine, iron, magnesium, copper, and zinc (Hodges Tr. 2879; Grollman, Tr. 1662; Mickelsen, Tr. 2427–2430; Herbert, Tr. 9861, 9868, 9881; Krehl, Tr. 27, 216–27, WD–G–Ross, Q. & A. 15, 16; WD–G–Harrison, Q. & A. 20; Exhibit P–651).

22. The establishment of qualitative and quantitative limits on the composition of dietary supplements will reduce consumer confusion concerning choice of dietary supplements by ensuring a basically rational formula for all products (WD–G–Gullberg, Q. & A. 31, Weissenberg, Tr. 7737).

23. From among these nutrients, appropriate for inclusion in dietary supplements, certain basic vitamins and/or minerals should be included in all articles offered as multivitamin and/or multimineral supplements (Herbert, Tr. 9880–81). Conversely, certain vitamins and minerals are, scientifically, optional in terms of whether or not they should be included in a multivitamin and/or multimineral supplement (Herbert, Tr. 9882).

24. A gross excess of folic acid intake on the part of human beings can interfere with the diagnosis of pernicious anemia as it masks the hematological manifestations of vitamin B_{12} deficiencies. (Herbert, Tr. 9872–73.)

25. While people in the United States appear to have some understanding of the comparatively greater requirements for iron experienced by many women during their child-bearing years, this appears to have affected opinion about other nutrients, since well over a third of the population believes that women need more vitamins than men (Exhibit P–1151, page B13, questions 20, 20a, 21, 21a). However, when iron is not named, only 16 percent of the population expresses an opinion that there is any difference in the mineral requirements of men and women (Exhibit P–1151, page B14, question 22).

26. All vitamins are specific chemical compounds. Each has the same composition and effect whether it is synthetically produced or derived from natural sources. (Grollman, Tr. 1758–1759; Mickelsen, Tr. 2471; Hodges, Tr. 2958–2959, 2962; Herbert, Tr. 9937–9938; WD–G–Harrison, Q&A 36).

27. It is pharmacologically necessary to allow, in a standard of identity for dietary supplements, for the inclusion of preservatives, stabilizers, colors, sweeteners, seasoning, carriers, bases, vehicles, and other substances which facilitate preparation of the product. However, no greater quantity of any such substances should be allowed to be included than is necessary to establish the desired physical or technical effect. Furthermore, the biological availability of the nutrients in the dietary supplement should not be impaired by the presence of such substances. (Grollman, Tr. 1752; Garrett, Tr. 11039).

28. Lack of a common language for identifying nutrients in dietary supplements has resulted in use of highly in-

appropriate names, having no or imprecise scientific meaning. The resultant wide variation in the manner of qualitatively naming and quantitatively declaring the nutrients in a dietary supplement on its label also extends to artificial colors, artificial flavors, and preservatives used in producing the supplement. (Grollman, Tr. 1698–1699, 1724; Herbert, Tr. 9891, 9896–9897; Weissenberg, Tr. 6623–6626, 8763–8764, 8789–8791; Exhs. P–113, P–161, P–311, P–95, P–152).

29. The use of standardized common names for various forms of dietary supplements will aid in more fully informing purchasers of the nature and value of these articles. The following common names are scientifically meaningful and accurate designations for the various supplements involved:

(a) "Multivitamin and multimineral supplement", for a dietary supplement which contains all of the mandatory vitamins and mandatory minerals listed in the table under § 80.1(f).

(b) "Multivitamin supplement", for a dietary supplement which contains all of the mandatory vitamins listed in the table under § 80.1(f).

(c) "Multimineral supplement", for a dietary supplement which contains all of the mandatory minerals listed in the table under § 80.1(f).

(d) "Multivitamin and iron supplement" or "multivitamin supplement with iron", for a dietary supplement which contains all of the mandatory vitamins listed in the table under § 80.1(f) plus the mineral iron.

(e) "_____ supplement", for a dietary supplement which contains a single vitamin or mineral listed in the table under § 80.1(f), the blank to be filled in with the name of the vitamin or mineral which the supplement purports or is represented to contain. (Grollman, Tr. 1753; Hodges, Tr. 2945–54; Mickelsen, Tr. 2487; Herbert, Tr. 9882, 9884–91; WD–G–Ross, Q&A 28–33; WD–G–Harrison, Q&A 30–33.

30. It is scientifically correct and necessary for the purpose of determining the value of a dietary supplement as a food which is purported to be or is represented for a special dietary use that the label thereof bear a statement stating the amount and percentage of the recommended daily allowance of each vitamin and/or mineral which the supplement contains in a specified daily quantity, such a statement being given for each consumer group for which the supplement is offered (Herbert, Tr. 9944–9946; Grollman, Tr. 1762; Hodges, Tr. 2964–2967; WD–G–Ross, Q&A 63; Mickelsen, Tr. 2685–2687). It is also necessary that clear directions for frequency of ingestion be stated on the label (Grollman, Tr. 1758; Hodges, Tr. 2955–2956; Herbert, Tr. 9937).

31. Reasons for a consumer desiring to know the sources of the nutrients in a dietary supplement include: (1) A medical need to have exact knowledge of all potential allergens encountered by a patient (WD–23–Kailin, Q&A 22; Lowe, Tr. 12579); and (2) religious or philosophical needs to know the components of one's total diet (WD–58–Morgan; WD–58–Prazenka; WD–58–Pietz; WD–23–Desmond; WD–23–Singer; WD–58–Pelc; WD–58–Curtis; WD–58–Taylor; WD–32–Hill).

32. Many dietary supplements include named ingredients which are of no value as supplements to the human diet (Grollman, Tr. 1626, 1675–77, 1707, Exhibit P–125; Mickelsen, Tr. 2464–65 (Exhibit P–172), 2469 (Exhibit P–173); Hodges, Tr. 2933 (Exhibit P–179), 2936, (Exhibit P–180); Herbert, Tr. 9891 (Exhibit P–113), 9899 (Exhibit P–468; Swain, Tr. 185–191, 213, 220, 221, 223, 229–231, 255, 264, 269, 336, 397, 442, 447, 455, 469, 475, 476, 487; Weissenberg, Tr. 8761, 6402, 5949, Exhibits P–576, P–591). However, many consumers will purchase such products with long lists of ingredients, believing them to be of better value than products with a lesser number of ingredients (WD–G–Perloff, Q&A 38–41; Exh. P–1151, page B9, questions 13, 14). Such consumers believe that if an ingredient is listed, it must significantly contribute to the value of the product as a dietary supplement (WD–G–Perloff, Q&A 18, 19; Exh. P–737). The label of a dietary supplement, as a food for special dietary use, should bear a statement of usefulness consisting of a list of the nutrient ingredients which provide the special use characteristics. The list of such ingredients should be limited to those which are of significant value and need in human nutrition as components of dietary supplements (Grollman, Tr. 1766; Hodges, Tr. 2969–2970; Mickelsen, Tr. 2518–2520; WD–G–Moses, Q&A–33; WD–G–Ross, Q&A 59–61).

33. A large proportion of the population of the United States is likely to choose dietary supplements, the ingredients of which are described as "natural" or from "natural sources", on the basis that "natural" constituents are superior to "synthetic" constituents (WD–G–Perloff, Q&A 44–46; Exhibit P–1151, pages B–10 and B–11, questions 16, 16a, 16b). There are many dietary supplements on the market which stress the "natural" source of their constituents (Swain, Tr. 234, 477; Weissenberg, Tr. 6554–6556, 8757–8758; Exhibits P–6, P–35, P–40–43, P–54, P–66–68, P–70, P–74), although this fact is of no nutritional significance (Grollman, Tr. 1758–1759; Mickelsen, Tr. 2471; Hodges, Tr. 2933, 2958–2959, 2962; Herbert, Tr. 9937–9938; WD–G–Harrison, Q&A 36).

34. It is medically and nutritionally appropriate to identify, on the label, chemical preservatives used in a dietary supplement, as well as to indicate on the label that artificial sweetener, artificial coloring, or artificial flavoring has been added to the article, if such is the case. In addition to these and the identification of the nutrients in the supplement, there is also the necessity for identifying alcohol, if present (Grollman, Tr. 1758; Hodges, Tr. 2956–2957; Herbert, Tr. 9941–9942). When alcohol is included as an ingredient in a dietary supplement, it is necessary, from a medical point of view, that the amount of alcohol contained in the dietary supplement by expressed on the label as a percent by volume (Grollman, Tr. 1705, 1760–1761; Hodges, Tr. 2956; Herbert, Tr. 9942).

35. Dietary supplements have been found on the market containing levels of vitamins below declared strength (Weissenberg, Tr. 8769–8770; Deutsch, Tr. 11147–11151; Garrett, Tr. 10986). Under certain ordinary and usual conditions of shipment, storage, and shelf-life, some vitamins and minerals in dietary supplements deteriorate, affecting the nutritional quality of the supplement (Grollman, Tr. 1761; Mickelsen, Tr. 2489; Hodges, Tr. 2963–2964; Herbert, Tr. 9942–9943; Garrett, Tr. 10943 et seq.). Based upon known rates of deterioration, it is technologically feasible to determine an appropriate expiration date for dietary supplements beyond which they should not be sold in the event deterioration actually occurs (Garrett, Tr. 10981 et seq.; Exhs. P–659, P–660). In the interest of consumers, it is reasonable and necessary to require that a manufacturer, packer, or distributor of dietary supplements containing vitamins and/or minerals determine an appropriate expiration date for his product, based on deterioration data under specified or customary conditions of handling and storage as indicated on the label, and that the expiration date be indicated when the supplement is offered for sale. (Garrett, Tr. 10978–10981, 11013–11015; Grollman, Tr. 1762; Hodges, Tr. 2963–2964; Mickelson, Tr. 2489–2490; Herbert, Tr. 9943; WD–G–Gullberg, Q&A 17, 33; WD–G–Ross, Q&A 40–42; WD–G–Harrison, Q&A 34, 35).

36. The following table represents a reasonable and scientifically accurate adaptation of the 1968 Recommended Dietary Allowances as published by the Food and Nutrition Board of the National Academy of Sciences-National Research Council (WD–3A–Sebrell, Q&A 15). Upper and lower limits for the listed nutrients are appropriate for dietary supplements of vitamins and minerals (Herbert, Tr. 9900–04, 9867; WD–G–Ross, Q&A 17, 18; WD–G–Harrison, Q&A 22, 24; Boehne, Tr. 2764; WD–3A–Sebrell, Q&A 26, 27, 39).

U.S. GOVERNMENT RECOMMENDED DAILY ALLOWANCES (U.S. RDA's) AND PERMISSIBLY COMPOSITIONAL RANGES FOR DIETARY SUPPLEMENTS OF VITAMINS AND MINERALS

	Unit of measurement	Infants and children under 4 years of age, U.S. RDA			Adults and children 4 or more years of age, U.S. RDA			Pregnant or lactating Women, U.S. RDA		
		Lower limit		Upper limit	Lower limit		Upper limit	Lower limit		Upper limit
Vitamins, mandatory:										
Vitamin A	International units	1,250	2,500	2,500	2,500	5,000	5,000	5,000	8,000	8,000
Vitamin D [1]	do	200	400	400				400	400	400
Vitamin E	do	5.0	10	15	15	30	45	30	30	30
Vitamin C	Milligrams	20	40	60	30	60	90	60	60	120
Folic acid [2]	do	0.1	0.2	0.3	0.2	0.4	0.4	0.4	0.8	0.8
Thiamine	do	0.35	0.7	1.05	0.75	1.5	2.25	1.5	1.7	3.0
Riboflavin	do	0.4	0.8	1.2	0.8	1.7	2.6	1.7	2.0	3.4
Niacin	do	4.5	9.0	13.5	10	20	30	20	20	40
Vitamin B_6	do	0.35	0.7	1.05	1.0	2.0	3.0	2.0	2.5	4.0
Vitamin B_{12}	Micrograms	1.5	3	4.5	3	6	9	6	8	12
Optional:										
Vitamin D	International units				200	400	400			
Biotin	Milligrams	0.06	0.15	0.22	0.15	0.3	0.45	0.3	0.3	0.6
Pantothenic Acid	do	2.5	5.0	7.5	5.0	10	15	10	10	20
Minerals, mandatory:										
Calcium	Grams	0.125	0.8	1.2	0.125	1.0	1.5	0.125	1.3	2.0
Phosphorus [3]	do	0.125	0.8	1.2	0.125	1.0	1.5			
Iodine	Micrograms	35	70	105	75	150	225	150	150	300
Iron	Milligrams	5.0	10	15	9.0	18	27	18	18	60
Magnesium	do	40	200	300	100	400	600	100	450	800
Optional:										
Phosphorus	Grams							0.125	1.3	2.0
Copper	Milligrams	0.5	1.0	1.5	1.0	2.0	3.0	1.0	2.0	4.0
Zinc	do	4.0	8.0	12	7.5	15	22.5	7.5	15	30

[1] Optional for adults and children 4 or more years of age.
[2] Optional for liquid products.
[3] Optional for pregnant or lactating women.

DISCUSSION OF PROPOSED FINDINGS

The standard of identity established in this document is closely related to the requirements for special dietary foods, for nutrition labeling, and for over-the-counter drugs. It is therefore important that the interrelationship of these various regulatory provisions, and the rationale behind their development, be fully understood.

The evidence at the 1968–70 Special Dietary Food Hearings strongly supported the position that all requirements for vitamins and minerals can be obtained from a well-planned diet of conventional foods, and thus that conventional foods always have been, and will continue to be, the principal source of nutrients in the daily diet. For this reason, 10 percent of the U.S. RDA of a nutrient is regarded as significant for purposes of labeling under § 1.17, and indeed the presence of even 2 percent of the U.S. RDA of a nutrient is permitted to be labeled because of the cumulative impact of these small amounts when ingested in several foods in the course of the day. These relatively small amounts of nutrients may not be significant in and of themselves, but when added together they are quite sufficient to provide the full complement of daily nutrition.

A dietary supplement product, on the other hand, is not intended to be eaten like any other constituent of the normal daily diet, but rather is intended, as the name states, to be taken to supplement the diet as insurance in the event that an individual's diet may not include a full complement of essential vitamins and minerals (e.g., it is often impractical to supply the iron needs of adult women with conventional foods). It would therefore be quite inappropriate for a dietary supplement to contain the relatively small amount of nutrients found in many foods; and conversely, it would be equally inappropriate to provide for fortification of conventional foods at substantial levels which would result in gross over consumption of vitamins and minerals in the diet. Therefore, with certain exceptions, a dietary supplement must contain at least 50 percent of the U.S. RDA of the nutrients involved, and any conventional food fortified in a way that any nutrient achieves a level of greater than 50 percent of the U.S. RDA will similarly be regarded as a dietary supplement subject to all of the requirements of the standard of identity. In short, the regulations provide a sensible and reasonable distinction between the customary way of obtaining nutrients in relatively small amounts in individual food items through the daily food supply, and the insurance provided by a dietary supplement containing relatively large amounts of those nutrients.

Substantial consideration was given to the appropriate ceiling for the nutrient levels in a dietary supplement. Evidence presented at the Hearings would have justified as low as 100 percent of the U.S. RDA. The Commissioner has concluded, however, with certain exceptions, that the additional assurance provided by permitting 150 percent of the U.S. RDA in a dietary supplement is warranted. This level will cover all known nutritional needs of normal individuals.

The Commissioner has also recognized that there are a number of products comprised of nutrients, intended to provide daily nutrition in a variety of medical conditions, which are represented for use solely under medical supervision in the dietary management of specific diseases and disorders or as the sole item of a meal or in the daily diet. Many of these foods are in a state of development, and standardization is not possible on the basis of the Hearings. Accordingly, although such products are required to be labeled in compliance with §§ 125.1–125.3, they are exempt from the requirements of § 80.1. Separate regulations will be promulgated when appropriate to control the composition or labeling of these foods.

The status of meal replacements has received special consideration. The Commissioner has concluded that it is appropriate to exempt them from labeling under § 125.3 and instead to require that they be labeled under § 1.17, unless they fall within the category of "medical foods" just described above. They have also been exempted from the requirements of § 80.1, since they are properly regarded as complete replacements for a meal and not as a dietary supplement, and since the nutrient levels established for dietary supplements would be too high for a product intended as a replacement for a single meal. The Commissioner is considering a nutrition guideline limiting the nutrient levels in meal replacements to no higher than 50 percent of the U.S. RDA for adults and children 4 or more years of age.

The Commissioner has also reviewed the question whether some products containing nutrients should be classified as drugs rather than as foods under the act. As already noted, the ceiling for nutrient content provided by § 80.1 will cover all known nutritional needs for normal individuals. Dietary supplementation at any higher level is clearly unwarranted. Accordingly, any vitamin-mineral product containing more than the upper limit of the U.S. RDA must be regarded as appropriate only for the treatment of vitamin-mineral deficiencies, or for some other medical purpose, and is properly classified as a drug. The Commissioner has previously announced in the FEDERAL REGISTER of May 11, 1972 (37 FR 9464, paragraph 94) that vitamin-mineral products which are drugs would be subject to the procedures for review of over-the-counter (OTC) drugs established in 21 CFR 130.301. The advisory review panel which considers these products will be provided all pertinent evidence and information relating to such products presented at the Special Dietary Food Hearings in addition to any other data and information submitted to it. That panel will be requested to provide its advice on safe and effective formulations and labeling of such products, and on the dividing line between OTC and prescription vitamin-mineral drug products.

The Commissioner also recognizes that foods represented solely for use under medical supervision in the dietary management of specific diseases and disorders (e.g., chemically defined diets for the nutritional support of individuals suffering from inborn errors of metabolism) represent an exception to the rule that nutrients included in products at levels greater than the upper limit of the U.S. RDA are drugs. At this time such "medical foods" should not be the subject of specific restrictions. Accordingly, the Commissioner has classified these

products as foods regardless of the nutrient levels they contain.

The lower and upper limits for any given nutrient in a dietary supplement have been, in general, set at 50 percent and 150 percent, respectively, of the U.S. RDA values (with 6 exceptions, discussed below). It is reasonable to allow for some variation in the amount of a nutrient in such a product, and the U.S. RDA is a good central point for the variation because it is an estimate of a pattern of daily nutrient needs for the U.S. population as established by scientific experts. Establishing 50 percent as the lower permissible limit provides protection for the consumer from inadequate amounts of nutrients for supplementation purposes. Establishing 150 percent as the upper permissible limit provides protection of the consumer from excessive amounts of nutrients for supplementation purposes. The upper permissible limits for vitamin A and vitamin D equal the specified U.S. RDA's for these nutrients to minimize their toxicological potential (see 37 FR 26618, December 14, 1972). For dietary supplements for pregnant or lactating women, the general principle establishing lower and upper permissible limits of composition is the specified U.S. RDA's for adults and children 4 or more years of age and twice these amounts respectively, with specific exceptions as discussed below.

In defining nutrient needs the Food and Nutrition Board of the National Academy of Sciences-National Research Council has recognized differences of opinion among experts as well as the paucity of information for some nutrients on which to base an opinion about dietary needs for humans. These facts, coupled with the need to offer the product technologist a degree of freedom in compounding dietary supplements, establish the reasonableness of having permissible ranges.

In considering dietary supplements it is reasonable to recognize two categories of products which consumers should have available to them. One is a product containing all the vitamins and/or minerals for which RDA's have been established because of the stated inability of the consumer to determine precisely what nutrients he needs (with or without the optional nutrients). The other is a product which contains only one nutrient for which RDA's have been established. The usefulness of this kind of product derives from the recognition of the need for the availability of single nutrients which may be recommended for dietary supplementation in any combination, and the inherent right of consumers to decide, on their own, what particular nutrient they may need to round out a "balanced diet." These decisions may be based on a complex set of information, knowledge, or biases, but benefit can be derived from such a choice and it should not be denied.

At the same time, the enormous variety of products possible as a result of the number of essential vitamins and minerals needs some simplification. A consumer cannot make a rational choice, for example, between one supplement with 10 vitamins and minerals versus another supplement containing a different combination of seven vitamins and minerals, and a third with only three or four vitamins present, but in substantially greater amounts. Section 80.1 thus permits full personal choice but reduces substantially the confusing array of combination products.

The recently completed study "The Ten-State Nutrition Survey, 1968–1970," Department of Health, Education, and Welfare, Health Services and Mental Health Administration, Center for Disease Control, Atlanta, Georgia, emphasizes widespread iron deficiency anemia. The Committee on Maternal Nutrition, NAS–NRC report, "Maternal Nutrition and the Course of Pregnancy: Summary Report" National Academy of Sciences, 1970, concludes that the widespread incidence of nutritional anemia and the increased iron requirements of pregnancy and lactation provide a need for iron supplementation in amounts up to 60 milligrams per day. This information justifies both this considerable increase in the upper limit for supplementation over the NAS–NRC RDA values for iron for pregnant or lactating women (18 milligrams) as reasonable in view of the more recent deliberations of the NAS–NRC, and the permitted combinations of vitamins and the mineral iron, under § 80.1 (21 CFR 80.1).

The Commissioner recognizes that there are currently on the market combinations of vitamins and minerals which do not contain all of the nutrients which are scientifically and medically appropriate for a dietary supplement, and/or do not contain the nutrients at adequate levels. Some of these products are used by consumers as a food component of their daily diet intake, in a way that is no different in principle than the use of fortified food. By establishing a standard of identity for dietary supplement (e.g., multivitamin and/or multimineral supplements), those products either containing more than one but less than all of the nutrients appropriate for inclusion in a dietary supplement, or containing any of these nutrients below the established dietary supplement range can no longer be marketed as dietary supplements.

The Commissioner has concluded that it is reasonable to permit the continued marketing of products containing less than all of the nutrients required as a dietary supplement, at levels appropriate for foods, when such products are properly labeled as foods. To maintain the right of consumers to obtain such truthfully labeled food products if they so desire, the regulations provide that such products will remain available, labeled pursuant to § 1.17 (21 CFR 1.17) (nutrition labeling). No labeling will be permitted that could be confused with dietary supplements.

Thus, the regulations provide that combinations of vitamins and minerals not meeting the requirements of the standard of identity in § 80.1 (21 CFR 80.1) can be marketed as foods if they do not contain in a single serving any of the permitted vitamins or minerals at levels greater than the lower limit established for dietary supplements in this section. Like any other food, such a product may not be labeled as a "dietary supplement" or use any terms which suggest to the consumer that the product can serve as a dietary supplement, and such product shall provide the information required under § 1.17.

Proprietary names, including those presently used, may be included on the label provided they do not infer in any manner that the product is a dietary supplement. If such a product is in other than conventional food form (e.g., a tablet or capsule), the common or usual name of the product must, in order to meet the requirements of § 1.8 (21 CFR 1.8), include a listing of the names of each of the vitamins and/or minerals present.

In addition to those combinations of vitamins and minerals containing levels less than the lower limits of nutrients required by § 80.1 (21 CFR 80.1), there are products which contain more than one, but not all, of the vitamins and minerals provided for in § 80.1, at levels within the upper and lower limits established therein. These products do not meet the requirements of dietary supplements as defined in this tentative order.

The Commissioner has carefully reviewed the record of the hearing in considering whether there is any medical or scientific justification for such combinations of vitamins and minerals other than those in this tentative order. No persuasive justification for additional combinations was presented at the hearing. The evidence strongly supported inclusion of all vitamins and/or minerals in a dietary supplement, thus eliminating the many bewildering combinations now found in the marketplace, for which there is neither medical support nor consumer understanding. Nor is the Commissioner aware of more recent scientific data supporting additional combinations as dietary supplements.

Nevertheless, it is recognized that, as scientific and medical information changes, some justification for a vitamin and/or mineral combination not permitted by this standard of identity may be brought forward. Accordingly, the Commissioner has concluded that it is reasonable to include in the standard a specific petition mechanism whereby requests may be made for inclusion of additional combinations. Such a petition would include scientific data of nutritional and technological nature to support the particular combination involved, together with the proposed name of the product and with labeling designed to differentiate the product from other dietary supplements and to be fully informative to the public.

The Commissioner will provide sufficient time to allow manufacturers to develop petitions for vitamin and mineral products currently marketed which do not comply with the requirements set forth in § 80.1. Such petitions must be submitted by December 31, 1973, unless the Commissioner extends this time. This

time period is sufficient for manufacturers to determine if there is adequate scientific and technological justification to submit a petition. Where the manufacturer can show good cause, a further extension of time will be permitted to develop the necessary information and to submit a petition. During any consideration of or proceedings with respect to any petition submitted, the Commissioner will also grant an extension of time upon reasonable request. When final action is taken on any such petition, the manufacturer will also be permitted sufficient time to make necessary changes in labeling or formulation of the product. The Commissioner concludes that this procedure is reasonable and in the public interest, in view of the importance of this new regulation. Regulatory action against products would, however, be taken against any false or misleading statements in the labeling as prohibited by 21 CFR Part 125.

Vitamins and minerals for which specific quantitative requirements in human nutrition have been established by the Food and Nutrition Board, except for vitamin D and phosphorus for certain groups, are considered as mandatory components in § 80.1. Vitamins and minerals for which only approximate quantitative requirements have been established are considered as optional components.

The adaptability of the human body to varying intakes of calcium makes the establishment of single "allowances" for this difficult. Many experts believe that 0.5 gram of calcium per day would provide a practical allowance for adults. However, the daily average intake in some industrially advanced countries is well above 0.5 gram per day, with 0.8 to 1.0 gram being a usual intake. Certain population groups have intakes up to 1.5 grams per day, and show no evidence of undesirable side reactions or failure of the body's ability to adjust. On the other hand, the FAO–WHO Expert Group on Calcium Requirements, in a comprehensive report "Calcium Requirements FAO–WHO," Rome, 1961, held the view that a calcium intake above 1.0 gram/day was unlikely to serve any physiologically useful purpose. Their recommendations for practical allowances for infants, children, and adolescents range from 0.4 to 0.7 gram/day.

The lower permissible limits for calcium, phosphorus, and magnesium are less than the limits that would result from applying the general principles because of the physiological and technological problems associated with their physical bulk. Phosphorus is not mandatory in dietary supplements for pregnant or lactating women because of evidence that supplemental phosphorus may increase the problem of leg cramps during pregnancy.

A ratio of dietary calcium to phosphorus of at least 1.0 is desirable to maintain balance of these major constituents of bones and teeth. The ratio in bones is about 2.0. However, this ratio is much lower in the soft tissues so that a ratio of at least 1.0 is reasonable. Consideration of the food supply, including its diversity, indicates the unlikelihood of achieving a ratio significantly greater than 1.0 in a normal well-balanced diet.

For these several reasons, the U.S. RDA for both calcium and phosphorus was set at 1.0 gram per day for adults. This subject needs additional research, and if future results indicate significant changes, the Commissioner will issue the required amendments.

Vitamin D is not mandatory in dietary supplements for adults and children 4 or more years of age because of its availability from vitamin D-fortified milk, its endogenous production, and the uncertainties of exogenous requirements for this group of consumers.

For the categories for adults and children 4 or more years of age and for pregnant or lactating women the upper permissible limits for folacin equal the specified U.S. RDA's for this nutrient to minimize the potential of gross amounts masking the hematological manifestations of pernicious anemia.

The actual amount of active component (of a nutrient) depends on the chemical form in which the nutrient is supplied. A table of reference forms for the water-soluble vitamins commonly used in different chemical forms is provided. For example vitamin B_6 denotes a collective term for a group of naturally occurring pyridines that are metabolically and functionally related—pyridoxine, pyridoxal, and pyridoxamine. Interconversion between the compounds is so active that there is little biological difference between them. However, each form has its own molecular weight and hence must be corrected back to a reference compound to avoid significant variations in quantitative declarations of vitamins present, as recognized in finding of fact No. 28. Thiamine nitrate is a commonly used form of thiamine. Its molecular weight is 327.36. The reference form, "thiamine chloride," has a molecular weight of 300.82. The hydrochloride has a molecular weight of 337.27. Thus, the actual amount of the active form can be readily calculated from the ratio of the respective molecular weights. Niacin (mol. wt. 123.11) is commonly supplied as niacinamide (mol. wt. 122.13), the difference in this case being negligible. The statement of standard recognized chemical compounds provides a sound reference for establishing the actual amount of a nutrient present in the various acceptable chemical forms of a given nutrient.

The Commissioner recognizes that the listing of nutrient ingredients is not in compliance with 21 CFR 1.10, in that they are not required to be listed in order of decreasing predominance. Vitamins and/or minerals in dietary supplements offered as tablets, capsules, wafers, powders, or other similar uniform units, shall be listed in the order as provided in the table under § 80.1(f). If vitamins and/or minerals are offered in the physical form of a conventional food (e.g., physical form of a breakfast cereal), and are added to a food so that a single serving provides 50 percent or more of the U.S. RDA of any one of the added vitamins and/or minerals, unless such addition is permitted or required in other regulations (e.g., a standard of identity or nutritional quality guideline), the labeling shall conform to the requirements of 21 CFR 1.17, in addition to this section.

Proposed Conclusions of Law

Based on the foregoing statements in conjunction with the findings of fact herein published the Commissioner concludes, that:

1. It will promote honesty and fair dealing in the interest of consumers, and will assist in carrying out the purpose of the law of providing full information to consumers as to the value of such foods for special dietary use, to promulgate a standard of identity for dietary supplements of vitamins and minerals as hereinafter set forth in § 80.1.

2. Such standard should limit the nutrients contained therein to those listed in § 80.1(f).

3. Such standard should limit the lower and upper amounts of nutrients supplied, to those listed in § 80.1(f).

4. The label of the dietary supplement should bear the statement as hereinafter prescribed by § 80.1(h), "multivitamin and multimineral supplement", "multivitamin supplement", "multimineral supplement", "multivitamin and iron supplement", or "multivitamin supplement with iron", or "---------- supplement" (the blank to be filled in with the name of the vitamin or mineral which the supplement purports or is represented to contain). In addition, such standard should specify the nutrients which shall comprise "multivitamin and multimineral supplements", "multivitamin supplements", "multimineral supplements", " multivitamin and iron supplements", or "multivitamin supplements with iron", and single nutrient supplements as hereinafter prescribed by § 80.1(b).

5. The label of the dietary supplement should bear the name and amount of each vitamin and mineral supplied by the supplement as prescribed by § 80.1(i).

6. The label of the dietary supplement also should name the natural source or chemical form of the nutrient ingredients used.

7. The label of a dietary supplement containing one or more nutrients subject to deterioration should bear an expiration date which will assure that the supplement contains the full declared level of the nutrients when consumed.

Tentative Order

Therefore, on the basis of the foregoing findings of fact, discussion, and conclusions of law drawn therefrom: *It is ordered*, That the stay of effective date of § 80.1, which stay was promulgated December 14, 1966 (31 FR 15730), be ended and that § 80.1 be modified to read as follows:

PART 80—DEFINITIONS AND STANDARDS OF IDENTITY FOR FOOD FOR SPECIAL DIETARY USES

§ 80.1 Dietary supplements of vitamins and minerals; definition, identity, label statements.

(a) The dietary supplements of vitamins and/or minerals for which definitions and standards of identity are prescribed by this section are prepared and offered as tablets, capsules, wafers, or other similar uniform units; in powder, granular, flake, or liquid form; or in the physical form of conventional foods; and purport to be or are represented for special dietary use by man to supplement his diet by increasing the total dietary intake of one or more of the essential vitamins and/or minerals specified in paragraph (f) of this section. The dietary supplements of vitamins and/or minerals are henceforth referred to as "dietary supplements" in this section.

(b) Classifications of dietary supplements.

(1) A dietary supplement shall contain only those vitamins and/or minerals listed in paragraph (f) of this section and shall be offered for its vitamin and/or mineral content only in the following combinations, with the provision that any vitamin or mineral defined as optional in paragraph (f) of this section may be omitted:

(i) All vitamins and minerals.

(ii) All vitamins.

(iii) All minerals.

(iv) All vitamins and the mineral iron.

(v) Vitamin D may be included in a multivitamin supplement and phosphorus may be included in a multimineral supplement without requiring the inclusion of the additional optional ingredients. The inclusion of any of the other optional ingredients (biotin or pantothenic acid for vitamins and copper or zinc for minerals) requires the inclusion of both such optional ingredients if the product is a multivitamin or multimineral supplement, and requires the inclusion of all four such ingredients if the product is a multivitamin and multimineral supplement.

(2) A dietary supplement may also be composed of any single vitamin or mineral listed in paragraph (f) of this section.

(3) Folic acid is optional for liquid dietary supplements because of instability of the vitamin in liquid preparations. Liquid dietary supplements containing multivitamins but not containing folic acid shall bear the following statement on the label, "This product does not contain the essential vitamin folic acid" which shall immediately follow the listing of vitamins, and minerals as prescribed in paragraph (i) of this section.

(4) Addition to or amendment of the list of permissible combinations of vitamins and/or minerals contained in paragraph (b)(1) of this section may be proposed by the Commissioner of Food and Drugs, on his own initiative, or upon petition by an interested person in accordance with the procedures set forth in Part 2 of this chapter. Any such petition shall be submitted in the form set forth in § 2.65 of this chapter, and shall include scientific data of a human nutritional and/or technological nature to support such addition or amendment as being consistent with the definition and purpose of dietary supplements as described by this section. The Commissioner, upon request, may extend the effective date of this section with respect to any particular product or class of products pending consideration and any administrative or court proceedings relating to any such petition, and may set a new effective date upon completion of the matter.

(5) The provisions of this section shall not apply to any food which contains or consists of any vitamin or mineral listed in § 125.1 (b) and/or (c) of this chapter, or any combination thereof, provided that all of the following requirements are met: (i) No such nutrient is contained at a level higher than the lower limit established for that nutrient pursuant to paragraph (f)(1) of this section, (ii) No direct or implied representative is made on the label, in labeling, or in advertising that the product is a dietary supplement or is adequate or appropriate for supplementing the daily diet with essential nutrients, (iii) If the product is in other than conventional food form, the common or usual name of the product required pursuant to § 1.8 of this chapter includes the names of each of the nutrients included, and (iv) The product is labeled pursuant to the provisions of § 1.17 of this chapter.

(c) General definitions.

(1) Subject to good manufacturing practices, dietary supplements described in this section shall contain in the specified daily quantity no less than the lower limit nor more than the upper limit of any nutrient specified in paragraph (f) of this section for the group(s) for which the supplement is offered.

(2) For the purposes of this section, the term "daily quantity" means the quantity of a dietary supplement that shall be specified in the labeling of the dietary supplement for consumption in a period of 1 day, and which shall be an amount or number of units reasonably suitable for and practicable of consumption in 1 day.

(3) In the event a dietary supplement is offered for more than one specific group, the specified daily quantity for each group shall be stated separately on the label.

(d) The different groups described in § 125.1(b) of this chapter shall be designated as follows: For labeling purposes:

(1) Infants and children under 4 years of age,

(2) Adults and children 4 or more years of age,

(3) Pregnant or lactating women.

(e) This section does not apply to:

(1) Other standardized foods.

(2) Foods the composition of which is defined by other regulations or statutes.

(3) Any food represented for use as the sole item of a meal or of the diet.

(4) Foods represented for use solely under medical supervision in the dietary management of specific diseases and disorders.

(5) Raw agricultural commodities (including marine products) and fabricated and other conventional foods to which single or multiple vitamins and/or minerals are added to improve nutritional quality, unless the total level (including any naturally occurring amounts) of any added vitamin or mineral per single serving attains or exceeds 50 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age as specified in § 125.1(b) of this chapter, in which case the provisions of both this section and § 1.17 of this chapter shall apply. If the provisions of both this section and § 1.17 apply to a food, the labeling of such food shall conform to the labeling established in this section except that the labeling established in paragraph (c) of § 1.17 of this chapter, including the order for listing vitamins and minerals established in paragraph (c)(7)(iv) of that section, shall be used in lieu of the labeling established in paragraph (i)(1) of this section.

(6) Raw agricultural commodities (including marine products) which by their nature are sources of a specific vitamin(s) and/or mineral(s) at a level that, if it had been added, would have brought them within the definition of a dietary supplement. Such shall meet all the requirements of this section if they are represented as dietary supplements. Such foods may also be used as a source of specific vitamins and/or minerals in dietary supplements meeting the requirements of this section.

(7) A food with nutrients restored to pre-processing levels or added pursuant to § 1.8(e) of this chapter so that it is not nutritionally inferior to the food for which it substitutes and which it resembles.

(f) Permissible qualitative and quantitative composition of dietary supplements.

(1) The following table sets forth the permissible qualitative and quantitative composition of dietary supplements of vitamins and/or minerals:

U.S. GOVERNMENT RECOMMENDED DAILY ALLOWANCES (U.S. RDA's) AND PERMISSIBLE COMPOSITIONAL RANGES FOR DIETARY SUPPLEMENTS OF VITAMINS AND MINERALS

	Unit of measurement	Infants and children under 4 years of age			Adults and children 4 or more years of age			Pregnant or lactating women		
		Lower limit	U.S. RDA	Upper limit	Lower limit	U.S. RDA	Upper limit	Lower limit	U.S. RDA	Upper limit
Vitamins, mandatory:										
Vitamin A	International units	1,250	2,500	2,500	2,500	5,000	5,000	5,000	8,000	8,000
Vitamin D [1]	do	200	400	400				400	400	400
Vitamin E	do	5.0	10	15	15	30	45	30	30	60
Vitamin C	Milligrams	20	40	60	30	60	90	60	60	120
Folic acid [2]	do	0.1	0.2	0.3	0.2	0.4	0.4	0.4	0.8	0.8
Thiamine	do	0.35	0.7	1.05	0.75	1.5	2.25	1.5	1.7	3.0
Riboflavin	do	0.4	0.8	1.2	0.8	1.7	2.6	1.7	2.0	3.4
Niacin	do	4.5	9.0	13.5	10	20	30	20	20	40
Vitamin B_6	do	0.35	0.7	1.05	1.0	2.0	3.0	2.0	2.5	4.0
Vitamin B_{12}	Micrograms	1.5	3	4.5	3	6	9	6	8	12
Optional:										
Vitamin D	International units				200	400	400			
Biotin	Milligrams	0.06	0.15	0.22	0.15	0.3	0.45	0.3	0.3	0.6
Pantothenic Acid.	do	2.5	5.0	7.5	5.0	10	15	10	10	20
Minerals, mandatory:										
Calcium	Grams	0.125	0.8	1.2	0.125	1.0	1.5	0.125	1.3	2.0
Phosphorus [3]	do	0.125	0.8	1.2	0.125	1.0	1.5			
Iodine	Micrograms	35	70	105	75	150	225	150	150	300
Iron	Milligrams	5.0	10	15	9.0	18	27	18	18	60
Magnesium	do	40	200	300	100	400	600	100	450	800
Optional:										
Phosphorus	Grams							0.125	1.3	2.0
Copper	Milligrams	0.5	1.0	1.5	1.0	2.0	3.0	1.0	2.0	4.0
Zinc	do	4.0	8.0	12	7.5	15	22.5	7.5	15	30

[1] Optional for adults and children 4 or more years of age.
[2] Optional for liquid products.
[3] Optional for pregnant or lactating women.

(2) The U.S. Recommended Daily Allowances (U.S. RDA's) have been derived by the Food and Drug Administration from the "Recommended Dietary Allowances," published by the Food and Nutrition Board, National Academy of Sciences—National Research Council, and are subject to amendment from time to time as more information on human nutrition becomes available.

(g) Acceptable ingredient sources for dietary supplements:

(1) A vitamin or mineral used in a dietary supplement may be supplied by any suitable chemically synthesized or naturally produced substance which is not a food additive as defined in section 201(s) of the act; or if it is a food additive as so defined, it shall be used in conformity with regulations established pursuant to section 409 of the act.

(2) Any safe and suitable substance may be used as a preservative, stabilizer, flavor, sweetener, color, seasoning, carrier, base, or vehicle, or to facilitate preparation of the vitamin and mineral substances. A dietary supplement shall be prepared so that any such substance contained therein does not exceed the amount reasonably required to accomplish its intended physical or technical effect, and so that the biological availability of the vitamin(s) or mineral(s) is not impaired by the presence of such substance. Any such substance shall not be a food additive or color additive as defined in section 201 (s) or (t) of the act; or if it is a food additive or color additive as so defined, it shall be used in conformity with regulations established pursuant to section 409 or 706 of the act.

(h) Nomenclature.

(1) The common name of a dietary supplement shall consist of a term descriptive of the vitamin and/or mineral composition of the product, as established in paragraph (h)(2) of this section, together with a phrase or phrases designating the group(s) for which the supplement is represented, as established in paragraph (h)(3) of this section (e.g., "multivitamin and multimineral supplement for infants and children under 4 years of age"). The name of the dietary supplement shall appear prominently and conspicuously on the principal display panel(s) of the label. The letters of the phrase(s) designating the consumer group(s) for which the product is represented shall be no less than one-third the size of those used in the term descriptive of the composition of the product. In addition to the common name prescribed by this paragraph, a dietary supplement may be labeled with a proprietary name: *Provided*, That it is not false or misleading in any particular.

(2) The terms used to describe the vitamin and/or mineral composition of dietary supplements listed in paragraphs (b) (1) and (2) of this section shall be as follows: (i) "Multivitamin and multimineral supplement" for a dietary supplement containing all vitamins and minerals, (ii) "multivitamin supplement" for a dietary supplement containing all vitamins, (iii) "multimineral supplement" for a dietary supplement containing all minerals, (iv) "multivitamin and iron supplement" or "multivitamin supplement with iron" for a dietary supplement containing all vitamins and the mineral iron, (v) "————supplement" for a dietary supplement containing a single vitamin or mineral listed as a mandatory or optional ingredient in the table contained in paragraph (f)(1) of this section (the blank to be filled in with the name of the vitamin or mineral).

(3) The phrases used to designate the group(s) for which a dietary supplement is intended shall be as follows: (i) "For infants and children under 4 years of age," (ii) "for adults and children 4 or more years of age," and (iii) "for pregnant or lactating women."

(i) Format for listing vitamins and minerals, and ingredients: (1) Immediately following the name and group designation on the principal display panel, as required by paragraph (h) of this section, or on the information panel (21 CFR 1.8d) if insufficient space is available on the principal display panel, the label shall bear a listing in tabular from of each of the vitamins and/or minerals supplied by the specified daily quantity of the dietary supplement, such daily quantity being specified at the top of the list. The vitamins and/or minerals shall be described by the names appearing in paragraph (f) of this section, shall appear in the order listed in paragraph (f) of this section, and shall be grouped and identified separately as "vitamins" and/or "minerals" without reference to "mandatory" or "optional." The quantity of each vitamin and/or mineral present in a specified daily quantity of the dietary supplement shall be stated as a part of this list and expressed in percentage of the U.S. RDA for each specific group for which the supplement is offered. The quantity of each vitamin and/or mineral present in the specified daily quantity of the dietary supplement shall also appear in the tabular listing in terms of the units of measure specified in paragraph (f) of this section.

(2) For determining the percentage contents of the U.S. RDA's present in the dietary supplement, the quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Vitamin	Reference form		
	Name	Empirical formula	Molecular weight
Vitamin C	*L*-ascorbic acid	$C_6H_8O_6$	176.12
Folic acid	Pteroylmonoglutamic acid	$C_{19}H_{19}N_7O_6$	441.41
Niacin	Niacin	$C_6H_5NO_2$	123.11
Riboflavin	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Thiamine	Thiamin chloride	$C_{12}H_{17}ClN_4OS$	300.82
Vitamin B_6	Pyridoxine	$C_8H_{11}NO_3$	169.18
Vitamin B_{12}	Cyanocobalamin	$C_{63}H_{88}CoN_{14}O_{14}P$	1,355.40
Biotin	*d*-Biotin	$C_{10}H_{16}N_2O_3S$	244.31
Pantothenic acid	*D*-pantothenic acid	$C_9H_{17}NO_5$	219.23

(3) The following synonyms may be added in parentheses immediately following the name of the vitamin in the statement described in paragraph (i) (1) of this section:

Vitamin	*Synonym*
Vitamin C	Ascorbic acid.
Folic acid	Folacin.
Riboflavin	Vitamin B_2.
Thiamine	Vitamin B_1.

(4) A separate list of nutrient ingredients in the product shall be included on the label pursuant to the requirements of Part 1 of this chapter. Such list shall include the natural source or chemical form of each individual nutrient present in the dietary supplement.

(j) When the dietary supplement is in liquid form and contains alcohol, the label shall state the percent-by-volume of alcohol present.

(k) A dietary supplement containing one or more nutrients, subject to deterioration below the labeled value before consumption shall bear on its outside wrapper or container, as well as on the label of its immediate container, the statement: "Expiration date ———", the blank to be filled in by the month and year. The expiration date shall be the date selected by the manufacturer, packer, or distributor of the dietary supplement on the basis of tests or other information showing that the dietary supplement, until that date, under the conditions of handling, storage, and use prescribed by directions appearing on its label, or, in the absence of such prescribed directions, under customary or usual conditions of handling, storage, and use will contain not less than the quantity of each vitamin and/or mineral, as set forth on its label, when consumed.

(l) All labeling information required by this section shall comply with the conspicuousness required by section 403(f) of the act and § 1.8d of this chapter. In addition, the following labeling requirements shall be met.

(1) The list of nutrients required by paragraph (i) (1) of this section shall appear in uniform type size.

(2) The synonyms permitted by paragraph (i) (3) of this section, if used, and the list of nutrient ingredients required by paragraph (i) (4) of this section shall appear in uniform type size, and in type size no larger than that used for the list of nutrients required by paragraph (i) (1) of this section.

(m) In addition to the requirements of this section, the labels and labeling for a dietary supplement is subject to the prohibitions contained in § 125.2(b) of this chapter.

(n) All labeling for dietary supplements that is ordered after December 31, 1973, and all labeling used for such products shipped in interstate commerce after December 31, 1974, shall comply with the provisions of this section; and if not so labeled, such product shall be deemed to be misbranded under section 403 (a), (g), and (j) of the act.

Any interested person whose appearance was filed at the hearing may, on or before March 20, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, room 6–88, 5600 Fishers Lane, Rockville, MD 20852, written exceptions thereto. Exceptions shall point out with particularity the alleged errors in the proposed findings of fact and tentative order, and shall contain specific references to the pages of the transcript of testimony and to the exhibits on which the exceptions are based. Exceptions and accompanying briefs should be submitted in quintuplicate.

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.73-996 Filed 1-18-73;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

FOOD LABELING

Notice of Opportunity for Exceptions and Comments

The Commissioner of Food and Drugs is publishing in this issue of the FEDERAL REGISTER the following proposals, tentative orders, and regulations, with opportunity for the public to present exceptions and comments.

1. *Nutrition labeling.* A new 21 CFR 1.17, governing nutrition labeling for all food, is published as a final regulation. The Commissioner announced at the meeting of the National Food Advisory Committee on October 30, 1972, that additional time for public consideration of these regulations would be provided. Accordingly, the Commsisioner is requesting submission of any additional comment on this regulation on or before February 20, 1973. Any technical changes justified by such comment will be the subject of further modification of the regulation and will be published prior to March 15, 1973. The Commissioner does not anticipate any major changes in this regulation.

2. *Food label information panel.* A new 21 CFR 1.8d, establishing a standard food label information panel, is published as a final regulation. Additional comment on this regulation may also be submitted on or before February 20, 1973.

3. *Food fat labeling.* A new 21 CFR 1.18, governing the labeling of the fatty acid composition and cholesterol content of fat-containing food, is published as a final regulation and 21 CFR 3.41 is revoked. Additional comment on this regulation may also be submitted on or before February 20, 1973.

4. *Special dietary food regulations.* The tentative order on amendments of 21 CFR 125.1–125.3, relating to labeling of special dietary foods, is published in accordance with 21 CFR 2.97. Exceptions to this proposed order may be filed on or before March 20, 1973.

5. *Standard of identity for vitamin-mineral supplements.* The tentative order on a new 21 CFR 80.1, establishing a standard of identity for vitamin-mineral supplements, is published in accordance with 21 CFR 2.97. Exceptions to this proposed order may be filed on or before March 20, 1973.

6. *Food standard labeling changes.* Amendments to several standards of identity for enriched foods, to substitute reference to nutrition labeling in place of the existing reference to special dietary food labeling, are published as a proposal. Comments may be submitted on or before February 20, 1973.

7. *Food flavor labeling.* A revision of 21 CFR 1.12, to define spice and natural and artificial flavor and to establish a uniform pattern for labeling flavor and food to which flavor is added, is published as a proposal. Comments may be submitted on or before March 20, 1973.

8. *Incidental food additives.* Revision of 21 CFR Parts 1 and 5 including addition of a new § 1.10a, relating to exemptions from declaration of incidental ingredients, is published as a proposal. Comments may be submitted on or before March 20, 1973.

9. *Imitation food labeling.* A new 21 CFR 1.8(e), to govern application of the term "imitation" to food, is published as a proposal. Comments may be submitted on or before March 20, 1973.

10. *Standards of identity for mellorine and parevine.* Two new sections in 21 CFR Part 20, establishing standards of identity for mellorine and parevine requiring appropriate fortification and nutrition labeling, and revocation of 21 CFR 3.39, are published as proposals. Comments may be submitted on or before March 20, 1973.

11. *Label declaration of ingredients in standardized foods.* Section 3.88, which urges food manufacturers and distributors to utilize full ingredient declaration for standardized food labels, is clarified and republished.

12. *Uniform effective date for food labeling changes.* A request for comments on the establishment of a uniform effective date for food labeling changes that will be necessary as a result of promulgation of a number of new and revised regulations is published. Such comments may be submitted on or before February 20, 1973.

The Commissioner is publishing these proposals, tentative orders, and final regulations, at one time because many of them are interrelated and it is necessary that a uniform effective date be established for all. The Commissioner has carefully considered the time within which exceptions and comments must be received in order to proceed expeditiously with these matters, and has concluded that the periods set out above are reasonable. No requests for extensions will be granted.

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.73-998 Filed 1-18-73;8:45 am]

FOOD LABELING

Prospective Requirements for Manufacturers, Packers, and Distributors of Food; Request for Comments

The Commissioner of Food and Drugs is promulgating a number of regulations for packaged food, which are designed to furnish the consumer more information concerning the ingredients and nutritional qualities of packaged food, and to present such information in a uniform and readily understandable manner. Some of these regulations will make labeling changes mandatory, while others permit labeling changes on a voluntary basis. In some cases, moreover, these regulations will require extensive changes in current labeling, and the economic impact on the food industry, if these changes were required on a piecemeal basis over a period of time, might well be severe.

The Commissioner, therefore, is of the opinion that the mandatory effective date should be the same for all such regulations to provide an orderly and economical adjustment to the new labeling requirements. Such procedure would be in the interest of consumers as well as industry since it is likely that the cost of multiple, successive piecemeal label revisions, which would otherwise be required, would be passed on to the consumer in the form of higher food prices.

The following sections of the general regulations, under Title 21 of the Code of Federal Regulations, which are published elsewhere in this issue of the FEDERAL REGISTER, will implement some of these changes:

1. Section 1.8d *Food labeling; information panel.*

2. Section 1.17 *Food; nutrition labeling.*

3. Section 80.1 *Definition and Standard of Identity for dietary supplements of vitamins and minerals.*

4. Section 125.1 *Definitions and interpretation of terms.*

5. Section 125.2 *General label statements; dietary properties; placement.*

6. Section 125.3 *Label statements relating to vitamins and minerals.*

Other changes will be required through amendments in food standards, establishment of nutrition guidelines and common or usual names, and other regulations, some of which are published as proposals or final regulations elsewhere in this issue of the FEDERAL REGISTER.

In the past, in support of requests for time for making label changes required by newly promulgated regulations, industry has urged a lead time of 12 to 18 months for adjustment to mandatory labeling changes, because of the practice of certain segments of industry of ordering up to a 12-months supply of labels or labeled containers at one time, and because of the necessity of carrying a label inventory sufficient for several months production.

It is anticipated that the regulations in question will be promulgated within the next 6 months. In view of the multiple regulations involved in this case, and the time required for industry to redesign its labeling, obtain new labeling, and exhaust inventories of current labeling, the Commissioner proposes that a lead time of approximately 18 months for bringing products into full compliance is reasonable and proposes to provide until December 31, 1974, for full compliance for products shipped in interstate commerce.

The Commissioner also recognizes that there may be instances when an 18-month lead time will not be necessary for bringing particular products into compliance. Therefore, the Commissioner proposes to require that any affected product, for which labeling is ordered on or after December 31, 1973, comply in all respects with the provisions of these regulations at the time the labeling is placed into use, regardless of

time. Manufacturers are encouraged to order complying labeling and to begin using it at the earliest possible date.

In a policy statement (21 CFR 3.88) published in the FEDERAL REGISTER on March 10, 1972 (37 FR 5120), the Food and Drug Administration encouraged manufacturers, packers, and distributors, to voluntarily disclose in the labeling of food, complete information on the ingredients contained in the food and announced that "the Food and Drug Administration intends to amend the definitions and standards of identity of food by setting into motion, as rapidly as possible, the provisions of section 401 of the Act to require label declaration of all optional ingredients, with the exception of optional spices, flavoring, and colorings, which may continue to be designated as such without specific ingredient declaration." A clarification of this regulation is published elsewhere in this issue of the FEDERAL REGISTER. In addition, legislation requiring declaration of the mandatory ingredients in standardized foods has been initiated. The Commissioner urges that complete ingredient labeling be included at the same time that any labeling changes are made under any of the regulations which are the subject of this notice.

Interested persons may, on or before February 20, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this notice. Comments may be accompanied by a memorandum or brief in support thereof. Received comments maye be seen in the above office during working hours, Monday through Friday.

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.73-999 Filed 1-18-73;8:45 am]